TECHNICAL PROGRAM

19th Annual National Conference on Managing Environmental Quality Systems

EPA Initiatives in Quality Management: Quality and Environmental Information

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- "A Simple Approach for Assessing Data Quality Under a Performance-Based Measurement System" - Kevin Coats and Chung Rei Mao (U.S. Army Corp of Engineers, Omaha, NE)
- "Ethics Standards for Environmental and Petroleum Testing Laboratories" - Ann Rosecrance (Core Laboratories, Houston, TX)

2. Building Effective Quality Systems

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- "Development of a Quality Management System in a Small Environmental Testing Laboratory" - Denise K. McMillan (Army Engineer Research and Development Center, Omaha, NE)
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3. Topics in Analytical Laboratory Operating Practices

- "Verifying Data - EquE" - Silky Labie (Florida Department of Environmental Protection, Tallahassee, FL)
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- "Tracking Trends on Proficiency Testing Studies- A Helpful Tool for Assessing and Improving Data Quality" - Ann Rosecrance (Core Laboratories, Houston, TX)

4. QA Considerations in Environmental Data Operations: Planning, Implementation, and Assessment

- "Pre-QAPP Agreement (PQA) and Analytical Method Checklists (AMCs): Tools for Planning Research Projects" - Ann Vega (USEPA, National Risk Management Research Laboratory, Cincinnati, OH)

- "QA Resource Materials to Assist in Developing and Writing Research Plans" - Allan Batterman (USEPA, Mid-Continent Ecology Division, Duluth, MN) - Paper Not Available

- "Approaches to Systematic Planning for Environmental Operations" - Marguerite E. Jones (Dyncorp I&ET, Inc, Alexandria, VA)

5. Innovations in Quality Assessment Tools and Techniques

- "How Quality Assurance Shapes the Multi-Agency Radiation Survey and Site Investigation Manual" - Melinda Ronca-Battista (USEPA Radiation and Indoor Environments National Laboratory, Las Vegas, NV)

- "CLP Data Assessment Tool (DAT) - Innovations in Quality Assessment Tools and Techniques" - Dana Tulis (USEPA, OERR, Washington, DC)

- "The Augmented Auditor: The Electronically Enhanced Assessor - Wearable Computers for Audit" - Paul Mills (Dyncorp I&ET, Reston, VA)

- "Never Audit Alone - The Case for Audit Teams" - Nancy Adams (USEPA, APPCD/NRMRL, Research Triangle Park, NC)

6. Environmental Information Quality

- "Development of FORMS II Lite 4.0: A Rapid Prototype Approach" - Dana Tulis (USEPA, OERR, Washington, DC)

- "Using Data Management Tools to Improve Data Quality" - Hilary Price (American Management Systems, Fairfax, VA)

- "Integrating IT and QS: Information Technology and Quality Must Work Together" - Mark Doehnert (USEPA, Office of Radiation and Indoor Air, Washington, DC)

- "Validating Existing Data in the Environmental Technology Verification Program" - Shirley J. Wasson (USEPA, National Risk Management Research Laboratory, Research Triangle Park, NC)

7. Reconciling Measurement Quality Objectives

- "Software for Considering MQOs Within a DQO Framework" - Nancy Hassig (Battelle Pacific Northwest Division, Richland, WA) - Not Available

- "Automated Reconciliation of Data with Measurement Performance Criteria for Environmental Technology Verifications" - Principal Author: Robert Wright (Research Triangle Institute, Research Triangle Park, NC); Presented by: Malcolm Bertoni (Research Triangle Institute, Washington, DC)

- "A Practical Framework for Developing MQOs" - Daniel Michael (Neptune and Company, Albuquerque, NM)- Not Available

- "Collecting and Evaluating Secondary Research Information" - Douglas Fennell (USEPA, Research Triangle Park, NC) - Not Available

8. GIS: QA Considerations (Panel Discussion)

- "The EPA GIS-QA Team: Promoting Quality Assurance in the GIS Community" George M. Brilis (USEPA, NERL, ESD-LV, Las Vegas, NV)
- "Who, What, Why – Quality Assurance Issues in Dynamic GIS Environments" David Hansen (U.S. Bureau of Reclamation)
- "Geo-Referencing Initiatives" - Milo Anderson and Sarah Lehmann (Region 5) and Michael Plastino (USEPA, Office of Water)
- "Using GIS in Environmental Litigation - Applications, Solutions, and Quality Issues" - Robert J. van Waasbergen (President, Applied Environmental Data Services)
- "Metadata Information Management" - Cheryl Itkin (USEPA, NCEA, Washington, DC)
- "QA Considerations in GIS Information Management" - Karl Hermann (USEPA, Region 8, Denver, CO)
- "Spatial Accuracy as a Critical GIS-QA Element" - George M. Brilis (USEPA, NERL, ESD-LV, Las Vegas, NV)

$PM_{2.5}$ Mass Analysis Laboratory Pre-certification Program

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Since 1992, the California Air Resources Board's (ARB) Quality Assurance Section (QAS) has conducted system audits of laboratories performing PM_{10} mass analysis. These system audits have identified several common problems encountered by the various laboratories, many of which resulted in the invalidation of several years of PM_{10} data. With the promulgation of federal $PM_{2.5}$ air monitoring regulations which are much more stringent than those for $PM_{10,}$ the ARB initiated a program to avoid the loss of $PM_{2.5}$ air monitoring data and assure the quality of the $PM_{2.5}$ data. In 1998, the ARB implemented a $PM_{2.5}$ Laboratory Pre-certification Program. The QAS developed a laboratory pre-certification questionnaire that addressed those requirements a laboratory conducting $PM_{2.5}$ mass analysis determinations must follow. The questionnaire also included many, but not all, recommendations which would improve the overall quality of a laboratory's $PM_{2.5}$ operations. The requirements and recommendations are found in 40 CFR Part 50, Appendix L, U.S. EPA's Quality Assurance Handbook, Volume II, Method 2.12, and U.S. EPA's Model Quality Assurance Project Plan for the $PM_{2.5}$ Ambient Air Monitoring Program at State and Local Air Monitoring Stations. Pre-certification of California weighing facilities became a condition for submittal of $PM_{2.5}$ data to the U.S. EPA's Aerometric Information Retrieval System (AIRS) Air Quality Subsystem.

Pre-certification questionnaires were sent to those laboratories that planned on conducting $PM_{2.5}$ mass analysis. The laboratories had to submit the completed questionnaires to the QAS. The QAS reviewed the questionnaires and provided any comments back to the laboratories. Shortly thereafter, QAS staff scheduled an on-site visit and worked with laboratory staff to ensure that all requirements were met. The pre-certification program helped laboratories become aware of what was necessary to assure good quality data. All laboratories that were involved in the pre-certification program were granted pre-certification prior to the initiation of gravimetric analysis of $PM_{2.5}$ filters. All of those laboratories have also gone through subsequent system audits with no loss of $PM_{2.5}$ air monitoring data to date.

Introduction

In 1992, the Quality Assurance Section (QAS) of the California Air Resources Board (ARB) initiated a PM_{10} mass analysis system audit program for the laboratories in California conducting PM_{10} gravimetric analysis. During the system audits, the QAS enforced United States Environmental Protection Agency (U.S. EPA) requirements and guidelines, and assessed individual laboratory protocol. Some laboratories complied with the major U.S. EPA guidelines and requirements. Most laboratories, however, failed to meet some of the critical requirements, resulting in the invalidation of significant

amounts of PM_{10} data. Several common problems encountered by the various laboratories were identified through the QAS system audits.[1]

In July 1997, the U.S. EPA promulgated regulations requiring the $PM_{2.5}$ ambient air monitoring program to begin by January 1999. The $PM_{2.5}$ ambient air monitoring requirements, outlined in federal regulations,[2] are much more stringent than those for the PM_{10} air monitoring program. To avoid the loss of $PM_{2.5}$ ambient air monitoring data such as occurred with PM_{10} data, the ARB implemented a $PM_{2.5}$ Laboratory Pre-certification Program.

Background

The ARB is responsible for ensuring that air quality data in California meet State and federal requirements to be considered good quality data. Laboratories conducting particulate matter mass weighings must comply with quality control practices as outlined in the U.S. EPA's Title 40 Code of Federal Regulations (40 CFR) Part 58.[3] Specific requirements for PM_{10} and $PM_{2.5}$ filter weighings are found in the U.S. EPA's regulations,[2,4] the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II,[5,6] and the Model $PM_{2.5}$ Quality Assurance Project Plan.[7]

Since 1985, the QAS has conducted annual field performance flow rate audits for PM_{10} samplers. The warning limits for the flow rate audits were established as ± 7% to ± 10 % and the control limits at greater than ± 10 % difference from the true flow rate. The samplers' true flow rates also had to be within ± 10 % of the design actual flow rate of 40.0 cubic feet per minute. The PM_{10} flow rate audits periodically led to invalidation of PM_{10} data.

During the calendar year 1997, the ARB conducted 170 PM_{10} flow rate performance audits and found 95% of the samplers to be operating within the U.S. EPA's control limits (Table 1). As a result of the performance audit findings, samples representing 202 sample days were deemed invalid and deleted from the U.S. EPA's Aerometric Information Retrieval System (AIRS) Air Quality Subsystem. With some annual variations, these are typical results for flow rate performance audits.

# of Audits	# of Failures	Percent w/in Control Limits	# of Sample Days Deleted
170*	9	95	202

* Includes re-audits performed after corrective action due to initial audit failures.

Table 1. 1997 Performance Audits Summary

The QAS initiated system audits of laboratories in California conducting PM_{10} gravimetric analyses. The PM_{10} system audits entailed completion of a PM_{10} laboratory operations system audit questionnaire, an on-site inspection, and an assessment of staff, facilities, quality control programs, data and document control, as well as a performance audit of the PM_{10} filter weighing balance and relative humidity and temperature sensors.

Since 1992, the ARB has conducted 13 PM_{10} mass analysis laboratory system audits. The system audits have shown the mass analysis laboratories to be the major source of error in the PM_{10} program. To date, the ARB has deleted a total of 61,759 days of PM_{10} data for not meeting federal requirements (Table 2). The data deletions were due to several common laboratory deficiencies, including poor record keeping, inadequate filter equilibration (relative humidity and temperature), and missing duplicate weighings and balance calibrations. The total number of days of PM_{10} data deleted as a result of the laboratory system audit findings greatly exceeded that of sampler flow rate performance audits.

Laboratories Audited	Sample Days Deleted
4	0
9	61,759

Table 2. PM_{10} Laboratory System Audit Summary

Table 1 summarizes the flow rate performance audit results for only one calendar year, whereas, Table 2 summarizes the system audit results which, for each laboratory, covers several years. Though the performance audit and system audit results cannot be directly compared, it does demonstrate the magnitude of the differences uncovered through each program.

$PM_{2.5}$ Pre-certification Program

In response to the findings of the PM_{10} performance and system audits, the ARB focused attention and resources on laboratory operations for the $PM_{2.5}$ ambient air monitoring program and initiated a $PM_{2.5}$ Laboratory Pre-certification Program in 1998. Each laboratory had to successfully complete pre-certification before being allowed to submit $PM_{2.5}$ data to the U.S. EPA's AIRS.

In the winter of 1997, the ARB's Monitoring and Laboratory Division began meeting with the local air districts in California to coordinate the implementation of the $PM_{2.5}$ air monitoring program. Staff from the Inorganic Laboratory Section (ILS) and the QAS identified those districts most likely to establish $PM_{2.5}$ gravimetric analysis laboratories. The ILS and QAS shared information regarding the balance room and mass analysis requirements as well as what was necessary to set-up such a laboratory. Five $PM_{2.5}$ gravimetric analysis laboratories were established in California for calendar year 1999 to serve the 83 $PM_{2.5}$ air monitoring sites. There were an additional two laboratories that were established after the $PM_{2.5}$ sampling began, one in 1999 and the other in 2000.

The seven laboratories were established by the following agencies:

1. ARB
2. Bay Area Air Quality Management District
3. San Diego County Air Pollution Control District
4. South Coast Air Quality Management District

5. Ventura County Air Pollution Control District
6. Great Basin Unified Air Pollution Control District (established in 1999)
7. Mojave Desert Air Quality Management District (established in 2000)

The Pre-certification Program is very similar to the PM_{10} Laboratory System Audit Program (a questionnaire and an on-site inspection), but without the records review and quality control assessment. The laboratory pre-certification questionnaire[8] addresses those requirements a laboratory conducting $PM_{2.5}$ mass analysis determinations must follow. The questionnaire also includes many, but not all, recommendations which would improve the overall quality of a laboratory's $PM_{2.5}$ operations. Included in the questionnaire are various sections addressing staffing, quality assurance plans, standard operating procedures, equipment and environment, pre-sampling and post-sampling filter inspection and weighing, data handling, and data reporting. As part of the pre-certification process, the laboratories were required to submit the following items to the QAS:

- The $PM_{2.5}$ Quality Assurance Project Plan (final draft).
- Standard Operating Procedures (SOP) that include $PM_{2.5}$ filter processing and weighing.
- A record of a two-consecutive-week period indicating the filter equilibration room relative humidity (RH) and temperature were held within the control limits. The record had to demonstrate that the mean temperature was held constant (± 2EC standard deviation) between 20EC and 23EC , and the mean relative humidity was held constant (± 5% RH standard deviation) between 30% and 40% RH. (Laboratory requirements are outlined in U.S. EPA's $PM_{2.5}$ Mass Validation Criteria.[8])

The pre-certification questionnaire helps laboratories become aware of what is necessary to assure good quality data. During the on-site inspection, the QAS also conducted the following performance audits:

- Standard weight checks (50, 100, 150 mg) using a set of ASTM Class 1 standard weights to ensure that the microbalance measured within ± 0.003 milligrams of the actual weight.
- Temperature and RH sensor checks to ensure that the temperature sensor response was within ± 2EC of the actual temperature and the RH sensor response was within ± 2% RH of the actual relative humidity.

By August 1998, the $PM_{2.5}$ Laboratory Pre-certification questionnaires were sent to the first five laboratories. The ARB laboratory, operated by the ILS, was the first laboratory to successfully complete the pre-certification process. The QAS made a few recommendations to the various laboratories during the pre-certification process to improve laboratory operations. All five laboratories successfully completed the pre-certification process prior to the initiation of $PM_{2.5}$ sampling on January 1, 1999. In addition, during the 1999 calendar year, the Great Basin Unified APCD laboratory successfully completed the $PM_{2.5}$ Laboratory Pre-certification process. The Mojave Desert AQMD laboratory is currently in the pre-certification process for 2000.

$PM_{2.5}$ System and Performance Audit Results

After $PM_{2.5}$ sampling began and laboratories were in operation, the QAS began conducting the $PM_{2.5}$ laboratory system audits. The $PM_{2.5}$ laboratory system audit is similar to the pre-certification process but like the PM_{10} laboratory system audit includes a records review and quality control assessment in addition to the questionnaire, on-site inspection, and performance audits. In 1999, four laboratories passed the system audits without any loss of $PM_{2.5}$ data due to poor laboratory practices. The $PM_{2.5}$ laboratory system audits for the other laboratories are expected to be completed by June 2000.

During 1999, the QAS also conducted $PM_{2.5}$ sampler performance audits. Despite much stricter control limits for flow rate (± 4% of true actual flow rate and ± 5% of design flow rate), through the first three quarters of 1999 there were only three failures in 61 performance audits (Table 3). Two of the failures were by one sampler which failed both the control limit criteria.

# of Samplers Audited	# of PDT Failures	# of PDD Failures	Percent w/in Control Limits
61	2	1	97*

PDT- Percent difference from true flow rate
PDD- Percent difference from design flow rate
* One sampler failed both PDT and PDD criteria.

Table 3. $PM_{2.5}$ Performance Audit Results Summary for 1999 (Jan. - Sept.)

Conclusion

Though the U.S. EPA regulations do not require states or districts to perform system audits, the ARB has found these to be critical to identifying problem areas for data quality within the particulate matter air monitoring programs. The ARB $PM_{2.5}$ Pre-certification Program, also not required by U.S. EPA, has proven to be an invaluable tool in helping laboratories meet the substantive requirements in 40 CFR Part 50, Appendix L. Since the laboratories met the requirements and implemented good laboratory practices prior to the beginning of field sampling, laboratory deficiencies leading to invalidation of data have been avoided. The ARB is expanding the Pre-certification Program to include all new air monitoring programs, both field and laboratory operations. Avoiding problems during the early stages of a new program by clearly identifying requirements and applicable good laboratory practices is critical and will prevent valuable data from being lost.

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A Simple Approach for Assessing Data Quality Under a Performance-Based Measurement System

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A simple approach is proposed for assessing performance and data quality under a Performance-Based Measurement System (PBMS). The proposed approach compares performance data with project-specific Measurement Quality Objectives before selecting a laboratory for sample analysis. The approach emphasizes documented performance under specified protocols. A laboratory must establish and implement detailed standard operating procedures (SOPs) for all major operations and document the process and results. A laboratory demonstrates its performance through Method Detection Limit (MDL) studies, Laboratory Control Samples (LCS) analysis, and frequent analysis of blind real-world performance evaluation (PE) samples. Data generated and reported under the proposed approach have an estimated uncertainty that meets the reporting requirement for uncertainty of the new International Organization of Standardization (ISO) Guide 17025. This presentation discusses why and how to use the proposed approach to assess performance and data quality under a PBMS.

INTRODUCTION

The production of data of known and acceptable quality that meet project-specified Data Quality Objectives (DQOs) is a primary goal of every environmental sampling and analysis activity. EPA's Environmental Monitoring Management Council (EMMC) recommends using PBMS for environmental sample analysis. EMMC defines PBMS as "A set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner". To determine data quality needs, EPA developed a seven-step DQO process that provides project-specific limits on decision errors. Based on the data quality needs, before the fact one determines if a laboratory is qualified to perform the analysis and after the fact determines if the data produced is of acceptable quality.

It is noted that the data quality in many data packages is ambiguous or unknown so that the data usability may be judged limited or questionable. Typical data packages report analyte concentrations for all hits, "ND" or "<" signs long with quantitation/reporting limits for non-detects, and associated quality control (QC) data and the control limits. Typical QC data include analysis of calibration verification samples, blank samples, laboratory control samples (LCS), matrix duplicates (MD), matrix spikes (MS), and matrix spike duplicates (MSD), depending on the contract's specifications. These QC data and associated control limits should inform data users of the quality of sample data. However,

the origin or determination procedures of the quantitation/reporting limits and the QC control limits are often not clear or appropriate such that the data quality is unknown or misleading.

This presentation proposes a simple approach for assessing laboratory performance and data quality. The approach is based on the existing QA/QC platform that is adopted by most environmental laboratories and is applicable to both definitive and screening methods. Although both sampling and analysis errors affect the quality of environmental data, the following discussions focus on laboratory analytical errors on precision and bias.

THE PROPOSED APPROACH

The proposed approach emphasizes four key elements of conventional laboratory QA/QC operations.

(1) SOP Preparation
(2) MDL Study
(3) LCS Analysis
(4) Proficiency Testing

First, a laboratory must establish and implement detailed SOPs for all key laboratory operations that affect data quality and document the results of key operations. The SOPs and documentation provide an important aspect of scientific evidence and legal defensibility for reported data.

Second, a laboratory shall follow 40 CFR 136 Appendix B to establish MDLs for all target analytes. If all laboratories use the same procedure to determine MDLs, the MDLs would be a good universal indicator for evaluation of laboratory performance under known conditions. Based on MDLs, a laboratory determines the method quantitation limits (MQLs) and the concentration of the lowest, allowable calibration standards. The uncertainty of analytical data increases as analyte concentrations decrease and approach MDLs. The estimated relative uncertainty of analytes measured at a concentration of N times MDL would be:

$$\pm \frac{2\sqrt{2} \times 100}{N \times t_{(n-1,\ 0.99)}}\ \%$$

where $t_{(n\text{-}1,\ 0.99)}$ is the Student's t factor for a 99% confidence level and a standard deviation estimate from an MDL study with n-1 degrees of freedom [1]. At MDLs, the relative uncertainty would be about ±100%. The estimated relative uncertainty will be exceeded by the uncertainty of LCS recovery at higher concentrations. Due to the large uncertainty near MDLs, data biases at concentrations below MQLs would be assumed to be equal to the mean of LCS recoveries.

Third, a laboratory shall establish control charts for the recovery of LCSs (i.e., blank spikes). If all laboratories use equivalent LCSs, empirically established in-house control limits would be another good universal indicator for laboratory performance and data quality. Because of clean matrices of LCSs, the control limits should be treated as the minimal uncertainties for field samples. LCS control limits may also be used to estimate the uncertainty of analyte recovery from field samples. The uncertainty of the mean recovery of field samples could be estimated as:

$$\pm \frac{\sqrt{2} \times t_{(n-1,\ 1-\alpha/2)} \times F_{LCS} \times 100}{\%R} \ \%$$

where $t_{(n\text{-}1,\ 1\text{-}\alpha/2)}$ is the Student's t factor with n-1 degrees of freedom at 1-"/2 confidence level; F_{LCS} is the standard deviation of the percent LCS recovery; and $\%R$ is the mean LCS recovery [2, 3]. Because of wide variations of matrix interferences, data biases at concentrations below MQLs will be assumed to be equal to the bias of mean LCS recoveries.

Last, because LCSs are prepared with interference-free matrices, the laboratory performance on field samples must frequently be verified with blind real-world PE samples. Double blind PE samples are preferred to single blind PE samples. If a laboratory is able to pass double blind PE samples on a routine basis, the laboratory demonstrates its performance on field sample analysis.

The four elements provide a foundation for the proposed approach. Using MDLs and LCS recoveries to assess data quality of field samples assumes consistency and comparability among different laboratories. The procedures used for determination of MDLs and the control limits of LCS recoveries will affect the values of MDLs and control limits, and hence the estimate of data uncertainties. It is noted that many laboratories do not exactly follow 40 CFR 136 to determine MDLs and use different procedures to establish QC control limits. The remaining discussions address those variations and propose standardized protocols for determination of MDLs and control limits.

MDL STUDY AND USAGE

Although most laboratories follow Appendix B of 40 CFR 136 to determine MDL, there are some variations, which may affect the MDL values. According to 40 CFR 136, the determination procedures involve spiking seven replicate aliquots of reagent water or sample matrix with analytes of interest at a concentration within one to five times the estimated MDL. The seven aliquots are carried through the entire analytical process; the standard deviation of the seven replicate analyses is calculated; and the MDLs is determined as a product of the standard deviation and a one-tailed Student's t factor.

A common deviation of MDL studies is spiking too high to yield MDLs that are biased low. According to Appendix B of 40 CFR 136, the spike concentrations of the seven MDL spikes should be one to five times the estimated MDL for reagent water matrix and one to ten for clean solids or sample

matrices. Otherwise, adjust the spike concentrations and repeat the study until the ratios are within these ranges. Because MDLs are based on the variances at the measured concentrations, the validity of the ratios between spike concentrations and estimated MDLs should be verified by comparing the mean of the seven measured concentrations, instead of the nominal spike concentration, with the determined MDL.

Because MDLs in real-world matrices could be elevated, the validity of MDLs in sample matrices should be verified. Based on the definition of MDL presented in 40 CFR 136, there is a 1% probability that a sample with no analyte will produce a concentration greater than or equal to the MDL. However, there is a 50% probability that a sample with a true concentration at the MDL will be measured as less than the MDL. For this reason, the validity of MDLs in other sample matrices shall be checked with MDL check samples in sample matrices at Reliable Detection Limits (RDLs) [4]. RDLs are based on the 1% probability of false negatives and are equal to twice the MDLs.

A laboratory shall establish its method quantitation limits (MQLs) based on the determined MDLs. At MQLs, the analytical errors should be no less than calibration errors, which are equal to the acceptance criteria for initial calibration verification (ICV) or continuing calibration verification (CCV). The acceptance criteria are usually ±10% for inorganic or classical analyses and ±20% for organic analyses. MQLs should therefore be set at ten times MDLs for inorganic and classical analyses and five times MDLs for organic analyses. MQLs also determine the concentration levels of the lowest, allowable calibration standards.

Because of the large uncertainty and bias associated with measured concentrations near the MDL, EPA did not specify acceptable limits for analyte recovery in MDL studies. However, if there is an excessively low or high recovery, the determined MDLs may not be meaningful and an MDL check sample should be used to estimate the MDL. For example, an MDL of 5Fg/L based on 100Fg/L MDL spikes and 10% recovery is not acceptable, because one could not reliably detect a 10Fg/L spike if the recovery is 10%.

CONTROL LIMITS OF LCS RECOVERY

Laboratories usually use control charts to demonstrate that it is under statistical control at a specified confidence. The 99% confidence intervals of the mean are routinely used as the control limits if certain statistical assumptions (e.g., independent data, normal distribution, etc.) are met. The control limits reported in a data package could be based on contract or regulatory requirements, published method performance data, or laboratory in-house empirically established control limits. Using any of those control limits is acceptable as long as the laboratory has demonstrated its ability to achieve the limits on a routine basis.

Many laboratories often report project-specified control limits in data packages. To ensure that data meet project-specified control limits, many laboratories screen LCS recovery data with the specified limits. When LCS recovery is within the specified limits, laboratories consider the LCS recovery is acceptable; otherwise, reanalyze the LCS sample. If the second analysis passes, laboratories take no

further actions and report sample data and the specified control limits. If the second analysis fails, laboratories take corrective actions and reanalyze all associated samples. As long as each individual LCS recovery is within project-specified control limits, most laboratories consider their performances meet project-specified control limits. However, if those LCS recovery data are charted, the calculated control limits are frequently wider than the specified limits even though each individual data is within the specified limits. This infers that the laboratory performance does not meet project-specified limits and using project-specified control limits gives misleading information on laboratory performance and data quality. A laboratory should use statistical control limits to demonstrate its performance. The wider in-house control limits could be due to a small number of LCS recovery data, which often fail to meet statistical assumptions (i.e., normal distribution, independency, etc.) Slightly wider in-house control limits are anticipated and acceptable if the sample size is small; however, when more data points (i.e., $20) are available, the data should show a central tendency and empirically established in-house control limits should meet project-specified control limits as a proof of acceptable laboratory performance.

Technically, prediction intervals, instead of confidence intervals, should be used to establish control limits, because it is the uncertainty of the next data, instead of the existing data, that is to be determined [5]. Control limits based on prediction intervals are wider than those based on confidence intervals. However, most laboratories use 99% confidence intervals to set control limits that lead an impression of tighter control and cause data comparability concerns. It is often noted that some laboratories establish control limits based on very few (<10) data points and some based on several thousand data points collected over a period of several years. Very few data points will not provide reliable control limits as discussed above; however, using data points over extended time may not reflect the current laboratory performance either. In addition, many laboratories retain only acceptable LCS recovery data for control chart analysis so that the control limits are tightened over time. Eventually, the laboratories have to rerun LCSs frequently and the control limits are misleading. Obviously, a protocol for establishing and using control limits is needed to ensure the consistency and comparability of control limits for LCS recovery. The protocol should address the requirements for LCS concentration and matrix, sample size and distribution, outlier testing and treatment, statistical hypothesis and analysis, control chart updating and usage, etc. It is recommended that the protocols be established based on ASTM or ISO guides.

CONCLUSIONS

MDL and LCS recovery are two unique analytical parameters that most environmental laboratories routinely perform using the same procedures and equivalent samples. Because of their consistency and availability, MDL and LCS recovery could be used as universal indicators for evaluation of laboratory performance and data quality. The precision and bias of LCS that are determined based on control charts of LCS recovery data may be used to estimate the precision and bias of sample data. However, to ensure the data comparability, laboratories must explicitly follow specified protocols to determine MDLs and control limits for LCS recoveries. Laboratories should frequently run MDL check samples and blind PE samples to check the validity of MDLs in the sample matrix and laboratory performance on field samples. Laboratories must prepare and implement detailed SOPs for all key operations and

document the results. In-house SOPs on control charts and empirically established LCS control limits should be submitted for review of laboratory performance before sample analysis. The proposed approach is simple to implement for assessing laboratory performance and data quality.

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Ethics Standards for Environmental and Petroleum Testing Laboratories

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This paper discusses the need for ethics standards in environmental and petroleum testing laboratory and provides guidance on key elements that should be included in an effective ethics program. These elements include implementation of an ethics policy that is strictly enforced; requiring employees to sign an ethics agreement affirming their commitment to ethics and ethical conduct; development and implementation of ethics related policies and procedures; the role of a compliance or ethics officer; ethics assistance and reporting mechanisms; ethics communication and training; and compliance auditing. Examples of typical laboratory problems along with unacceptable solutions and acceptable solutions are presented in order to consider ethical and unethical ways to handle problem situations in the laboratory. By thinking out potentially compromising situations prior to their occurrence, the right choice can be made if and when they occur.

Background

Unethical behavior and actions have occurred in environmental and petroleum testing laboratories, despite the existence of laboratory supervision, quality assurance oversight, internal and external audits, and accreditation programs. Unethical conduct, such as intentional alteration of sample or calibration data, can turn into fraud and violation of one or more laws. The government takes fraud very seriously and will take administrative, civil and criminal action against both organizations and individuals that are suspected of committing fraud. Jail time and fines can be the unfortunate long-term consequences of making unethical short-term compromises. New measures are needed to ensure that laboratory employees are educated on the serious consequences of unethical conduct and on the important role of ethics in laboratory testing and data handling.

The need for ethics standards in environmental and petroleum testing laboratories is being recognized and is now included in the requirements for testing. The National Environmental Laboratory Accreditation Conference (NELAC) Standards (Quality Systems, Chapter 5, Section 5.6.2, 7/1/99) requires that ethics training be provided to technical staff at environmental testing laboratories that want to be NELAC accredited. The International Federation of Inspection Agencies (IFIA), Americas Committee, requires that petroleum testing laboratories have an ethics program in order to be a member of IFIA. Guidance is needed for laboratories seeking to implement an ethics program and train their employees in the importance of ethical conduct.

Introduction

Quality standards in analytical chemistry laboratories are well known and documented. In fact, quality requirements are included in laboratory quality assurance (QA) manuals and analytical methods. Laboratory QA programs include the components necessary to achieve acceptable data and assume

that behavior is ethical. However, standards for ethics are frequently not given the same attention and consideration as quality standards. Professional organizations have codes of ethics for their members, e.g., the American Chemical Society, American Society for Quality and American Institute of Chemists. These codes should carry over into work in the laboratory. However, ethical conduct in the chemistry laboratory is either assumed or not discussed. That is, until there is an unethical incident (ethics violation) that brings the need for ethics to the surface. Therefore, laboratories must also have an ethics program to communicate the expected conduct of employees, and describe what constitutes unethical behavior.

Ethics is a code of right and wrong that dictates personal and professional conduct. Ethical behavior is behavior that conforms to accepted professional standards of conduct; unethical behavior therefore is behavior not conforming to those standards. Fraud is an intentional act of deceit that may result in legal prosecution. Traditional laboratory QA programs have not adequately addressed ethics related matters because: 1) QA programs were not intended to address ethical or unethical behavior (they assume that behavior is ethical); 2) the scope of ethics transcends the matter of quality; and 3) QA programs deal with group activities rather than individual behavior. The decision to act ethically or unethically is an individual decision, not a group decision (although there have been instances where a group of employees acted unethically, it still was the individual's decision to act unethically.) Even the best laboratory QA program cannot ensure that employees will act ethically. Further, laboratory QA programs are not always effective in ensuring method and project compliance.

The unfortunate occurrences of unethical behavior in the laboratory community resulting in fraud are most likely due to either: 1) lack of ethics education and awareness prior to the fraudulent act (if analysts knew what could happen to them if they make unacceptable compromises, they would certainly not do it); or 2) lack of knowledge of confidence in appropriate ways to handle non-compliant data and problem situations. Unethical conduct in the laboratory does not generally occur when everything is going smoothly, it occurs when there are problems and pressure to achieve difficult or unrealistic objectives. The analytical community needs to do a better job collectively in educating laboratory analysts and technicians on the role of ethics in their work and in better ways to handle problem situations. Most individuals do not personally gain from committing an unethical act except to relieve some pressure that they feel, whether it is real or perceived. The impact of unethical behavior and fraud has been devastating to laboratories and laboratory employees, as well as to data users that must repeat entire projects if the original data is determined to be non-authentic. To better ensure that laboratory staff act ethically, an effective ethics program must be implemented in conjunction with the laboratory QA program.

Relevant Criminal Laws

An unethical action becomes a fraudulent act when the law is violated. For example, it is unethical if an analyst intentionally changes the instrument clock to make samples appear to be analyzed within holding time, when in fact they were not. It is unethical to intentionally manipulate instrument calibration or QC data to make the calibration or QC analysis meet an acceptance limit, when in fact the actual data were not acceptable. It is also unethical to intentionally alter sample data so that results appear to be "on-

spec" when in fact the results were "off-spec". An unethical act turn into a fraudulent act when falsified data is faxed or mailed to the client or other party. Faxing or mailing false information is an example of a violation under the laws relating to wire fraud or mail fraud, respectively. The sender could be charged with wire fraud or mail fraud, as well as making false statements if the work was done under a government contract. Relevant criminal laws that apply are as follows: False Claims – 18 U.S.C. § 287; False Statements – 18 U.S.C. § 1001; Mail Fraud – 18 U.S.C. § 1341; Wire Fraud – 18 U.S.C. § 1343; Conspiracy – 18. U.S.C. § 371; and Misprision (Concealment) of Felony – 18 U.S.C. § 4. Violations of these laws can result in substantial fines and imprisonment for up to five years. Press releases on laboratory investigations and convictions demonstrate that multiple charges of fraud are filed against laboratories and personnel that report false information.

Ethics violations and fraud affect both individuals and organizations (private and public). Regulatory agencies (i.e., the U.S. Environmental Protection Agency) and law enforcement officials (i.e., State attorneys) aggressively pursue and prosecute both individuals and organizations found to be in violation of the law. Enforcement actions are increasing as well as the severity of penalties for environmental crimes. Companies can face three types of legal action if they break the law: 1) administrative action, 2) civil action and 3) criminal action. Administrative action can result in debarment or probation for five or more years. Civil action can result in large fines of up to several million dollars. Criminal action can result in prison sentences for business owners or management officials. All of these actions can seriously damage the reputation of a company, cause a loss of revenue and customer business, and result in shutdown of the affected office(s) of the company. Further, attorney costs can run in the hundreds of thousands of dollars to represent and defend an organization charged with fraud, regardless of the final outcome.

An individual who commits an unethical act and/or breaks the law can face serious disciplinary action up to and including termination. Civil and criminal action can be taken against the individual, resulting in large fines and prison and/or probation sentences. Company lawyers may not provide legal assistance to an individual who commits an unethical act that results in a fraud charge(s); the individual must then seek and pay for his own legal assistance which can be very expensive. Further, negative exposure hurts the individual's chances of ever getting a job in his field again. The moral of this story is that short-term compromises are never worth the long-term consequences. Ethical conduct is the best course of action.

Implementing an Ethics Program

Ethics References. Legal guidance documents and web sites are sources for ethics information, although they may not specifically relate to laboratory activities. Two recent EPA documents provide guidance on the deterrence and detection of laboratory fraud.[1-2] Related information is provided in other publications on data authenticity, compliance and ethics.[3-7]

Ethics Policy or Statement. An ethics program must have an ethics policy or statement. This policy or statement should define the company or organization's position on ethics and state what is expected of its employees or members with regards to ethical behavior. For example, a company's ethics policy

may include the following items: "All employees at all times shall conduct themselves and the business of the Company in an honest and ethical manner. Compliance with this policy shall be strictly enforced." The ethics policy should be documented and posted for all employees to view.

Employee Ethics Agreements. Employee commitment to comply with the ethics policy should be affirmed and documented on an Employee Ethics Agreement that each employee must sign as a condition of his or her employment. These agreements may be updated as needed and signed each year to reaffirm each employee's understanding of, and commitment to, ethical behavior. If an employee is found to be in violation of the company Ethics Policy or the signed Employee Ethics Agreement, the employee may be terminated immediately.

Ethics Communication. Ethics should be communicated often, verbally, in writing, and by example. Laboratory staff should consider and discuss ethics, addressing any questions to the appropriate parties. Supervisors and managers should be readily available to assist employees in managing problem situations (to prevent ethics violations), and they should act ethically at all times to set a good example for their employees. Corporate management should frequently discuss their commitment to ethics with their managers and employees. Ethics should be discussed at meetings and other opportunities where employees are present. Videos may be developed by corporate management to further communicate ethics to company employees. There are many opportunities to include ethics in writing. Ethics posters are one form of communication. Ethics standards and reference to appropriate ways of handling non-compliant data and problem situations should be included in the QA manuals and standard operating procedures. Reference to ethical behavior should be included in contracts, sub-contracts, employment applications, and project plans. Ethics information and questions on ethics knowledge can be included in training records.

Ethics Program Management. The ethics program should be managed by a senior management employee with the authority, skills and availability to perform such an assignment. The ethics program manager should report to upper management on a regular basis on the status of ethics activities within the organization. Companies and other organizations may also elect to form an Ethics Committee with members from their upper management staff or Board of Directors that meet on a regular basis to set ethics policy and discuss ethics related matters.

Ethics Procedures. Policies and procedures for ethical conduct and for reporting and investigating suspected ethics violations should be developed and included in the organization's policy and procedures manual. An ethics procedure should define ethical conduct and what constitutes unethical behavior and how it is handled. Disciplinary action for ethics violations, up to and including termination, should be stated in the ethics procedure. Fair procedures for reporting and investigating alleged unethical behavior should be included in an ethics reporting and investigation procedure. Ethics procedures as well as other company procedures should be accessible to all employees. The application of these procedures for handling suspected or actual ethics violations should be uniform and consistent for all employees.

Zero Tolerance Policy. Organizations should have a zero tolerance policy on unethical activities, scientific misconduct and intentional lack of compliance with required procedures. Unethical behavior would include intentional falsification of data or records, such as professional credentials, employment records, time sheets, sampling or sample handling records, laboratory worksheets or logbooks, instrument settings or data, sample results or data, and laboratory analysis reports. Intentional lack of compliance or deliberate lack of adherence to company and method requirements would apply to an employee that purposely did not follow required procedures for instrument calibration, quality control, standards and reagents preparation, sample handling, sample preparation and analysis, or data processing and reporting.

Laboratories may wish to go one step further and define specific actions in the laboratory that are unacceptable or unethical. This may be in the form of a policy that employees are required to sign as demonstration of their understanding and commitment to comply with it. While most laboratory procedures define what employees are required to do, this policy ensures that employees are educated as to what they are not allowed to do. Refer to Table 1 for examples of typical laboratory problems and both unacceptable and acceptable ways to handle each situation. Laboratories that are proactive in informing employees of what constitutes unethical behavior have a much better chance of preventing fraud than laboratories that do not.

Ethics Assistance and Reporting Mechanism. Organizations should a have a single point of contact for assisting employees with questions on ethics related matters and for reporting observations of suspected unethical behavior or business conduct. A "helpline" or "hotline" is such a mechanism where phone calls, faxes or other correspondence on ethics concerns, questions or reports of suspected unethical behavior can be directed and then addressed appropriately. The phone numbers and addresses for the helpline or hotline should be documented and readily available to all employees. The helpline or hotline can be manned by a senior management employee, such as the compliance program manager, or by an outside service. All inquiries should be acted upon in a prompt matter according to appropriate procedures.

Compliance Plan. A compliance plan is all of the procedures used for ensuring compliance with company, client and regulatory requirements. The compliance plan should include or refer to policies and procedures on business conduct, especially ethics. Also include or refer to technical and quality assurance procedures used by the laboratory and required by client, method or regulatory agencies to ensure that data are accurate and traceable. The compliance plan should further include or refer to environmental management activities and procedures used for chemical and waste handling to comply with federal, state and local regulations. A compliance plan may also include a quality management program such as ISO 9002, and quality standards for laboratories such as ISO Guide 25 (to become ISO 17025) or the NELAC quality system standards.

Ethics Training. Ethics training should be provided to all employees and include, at a minimum, training on the organization's ethics policy and procedures. Ethics training should communicate the organization's expectations on ethical conduct and include examples of unethical activities and their impact (i.e., civil and criminal penalties) to demonstrate that short-term compromises are not worth the

long-term consequences. Questions or tests to verify understanding of the ethics requirements should be part of the training course. Ethics training should be documented on training forms and included in the employee training or personnel files. Training on laboratory procedures should be ongoing and based on each individual and their work assignments. Additional training on solving problems and managing work loads is critical to assist analysts in proper preventive/corrective action on analytical problems and the use of appropriate techniques for achieving desired productivity goals.

Compliance Audits. Adherence to the compliance plan, ethics program and associated procedures/requirements should be checked on a regular basis via compliance audits. The compliance officer, quality assurance staff or outside consultants may conduct compliance audits to determine if the ethics policy and procedures are being followed as well as technical and environmental management procedures. Any findings of non-compliance with company, client or government requirements should be documented and provided to company management. Immediate and appropriate action should be taken on any serious findings, up to and including issuance of a Stop Work Order on the affected areas. Prompt and effective preventive/corrective action should be taken on all findings and reported back to the auditing body for review and approval with copies provided to management. Verification of preventive/corrective action implementation should be performed in a timely manner by the auditors to ensure that preventive/corrective action was complete and effective in addressing the audit findings. Any unresolved items should be reported to management for immediate action.

With ethics as an established goal, organizations should further strive to find ways to monitor and bench mark the ethical behavior of their employees.

Conclusion

Ethical conduct in the laboratory is not guaranteed by the sole reliance on laboratory QA programs that were not designed to address ethical matters. In spite of the existence of good laboratory QA programs, unethical practices have occurred in environmental and petroleum testing laboratories and data quality has suffered. A new approach is needed to ensure that ethics and ethical behavior is a foundation for the performance of all work in the laboratory. Ethics must be built individually and collectively into a laboratory organization. Each laboratory employee, including managers, must understand and commit to the code and perform his or her work in an ethical manner. Ethics awareness and the implementation of a comprehensive ethics program in analytical chemistry laboratories can help to ensure better data quality and prevent further unethical acts from occurring, thereby sparing any more laboratories, laboratory staff or clients from suffering the serious consequences of fraud. A comprehensive ethics program, based on the guidance provided in this article, in conjunction with an effective laboratory QA program, will provide a strong foundation for ethical conduct and improved data quality.

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Table 1. Typical Laboratory Problems and Unacceptable and Acceptable Solutions

Problem	Unacceptable Solution	Acceptable Solution
Lack of time or resources to perform testing	**Making up Data (Dry Labbing) or Other Information –** Creating data for an analysis that was not performed or creating information that is not true.	Analytical results for all samples and quality control (QC) must be based on actual analyses that were performed. Documented data must match actual data. Sampling information must be based on actual sampling events.
Holding time near or past	**Improper Clock Setting (Time Traveling) or Improper Date/Time Recording** – Resetting the internal clock on an instrument to make it appear that a sample(s) was analyzed within a specified holding time when in fact it was not. Alternately, changing the actual time or recording a false time to make it appear that holding times were met, or changing the times for sample collection, extractions or other steps to make it appear that they were performed at the correct time when in fact they were not.	The recorded date and time of collection, preparation or analysis must match the actual date and time that the action was performed. Documented dates and times must represent actual dates and times. Samples exceeding holding times must be reported as such; a case narrative is recommended.
DFTPP or BFB not meeting acceptance criteria	**Improper GC/MS Tuning** – Artificially manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria when in fact the criteria were not met.	GC/MS tuning data must be generated and reported according to proper techniques without manipulation to the peak or mass spectrum. Preventive/corrective action must be taken on data not meeting required criteria.
Calibration or QC data not meeting acceptance criteria	**Improper Peak Integration (Peak Shaving or Enhancing)** – Artificially subtracting or adding peak area to produce an erroneous area that forces data to meet specific QC criteria when in fact the criteria were not met.	Instrument peaks must be consistently integrated and reported according to proper techniques, generally baseline to baseline, valley to valley or a combination of the two. Peak area cannot be subtracted or added to force data to meet specified criteria. Preventive/ corrective action must be taken on instrument data not meeting required criteria.
Calibration or QC data not meeting acceptance criteria	**Improper Calibration/QC Analysis –** i) Performing multiple (more than two) calibrations or QC runs (including calibration verifications, LCSs, spikes, duplicates and blanks) until one analysis barely meets criteria, rather than taking needed preventive/corrective action after the second failed analysis, and not documenting or retaining data for the other unacceptable data. j) Using the incorrect (previous) initial calibration to make calibration verification data appear to be acceptable when in fact it was not acceptable when compared to the correct initial calibration. k) Discarding points in the initial calibration to force the	a) All calibration and QC data associated with sample analyses must be documented. Preventive/corrective action must be taken and documented if calibration and/or other QC criteria are not met. b) Acceptance of calibration verification data must be based on the correct initial calibration. c) Calibration points can only be rejected for inclusion in the calibration curve if a known error was made or if a statistical evaluation indicates that a point can be discarded. When multiple target analytes are included in each calibration standard, it may be necessary to discard selected upper or lower points for individual target analytes. Points can be discarded at the upper end of the curve if the linear range of the detector has been exceeded. For these cases, dilute samples that exceed the highest point of the

Problem	Unacceptable Solution	Acceptable Solution
	calibration to meet an acceptance criteria. l) Discarding points from an MDL study to force the calculated MDL to be higher or lower than the actual value.	calibration curve. Points can be discarded at the lower end of the curve if the detector is not producing a response. For these cases, the laboratory-reporting limit must be adjusted accordingly. Data points for MDL studies can only be rejected for inclusion in the MDL calculation if a known error was made or if a statistical evaluation indicates that a point can be discarded.
QC samples or spikes not meeting acceptance criteria	**Misrepresentation of QC Samples and Spikes –** Misrepresenting QC samples or spikes as being digested or extracted when in fact they were not actually digested or extracted. For example: a) Adding surrogates after sample extraction rather than prior to sample extraction. b) Reporting post-digested spikes or duplicates as pre-digested spikes or duplicates. c) Not preparing or analyzing method blanks and laboratory control samples (LCSs) the same way that samples are prepared or analyzed in order to make it appear that method blank or LCS results are acceptable when in fact they may not be.	QC samples and spikes must be prepared, analyzed and reported according to appropriate procedures. a) Surrogates must be added prior to sample extraction. b) Post-digestion spikes and duplicates must be reported as post-digested and must not be misrepresented as pre-digestion spikes and duplicates. c) Method blanks and LCSs must be prepared and analyzed the same way that samples are prepared and analyzed. Any QC results outside of acceptance criteria must be reported as such; a case narrative is recommended.
Calibration or QC data not meeting acceptance criteria	**File Substitution –** Substituting previously generated files (runs) for a non-compliant calibration or QC run to make it appear that an acceptable run was performed when in fact it was not.	All data must be generated and reported for actual analyses performed. Reported dates and times for all analyses must match actual dates and times. Substitution of files is not permitted.
Calibration or QC data not meeting acceptance criteria	**Unwarranted Manipulation of Computer Software –** Unwarranted manipulation of computer software to force calibration or QC data to meet criteria, and removing computer operational codes, such as "M" flag.	Computer manipulation is allowed only for warranted reasons and any manipulation should be minimal and traceable. Removal of computer operational codes is not permitted.
Analytical conditions for standard do not work for sample	**Improper Alteration of Analytical Conditions –** Improperly altering analytical conditions, such as changing the instrument conditions for sample analyses from those used for standard analyses. Also using different procedures to process sample data than those used for standards.	All sample analyses must be performed under the same conditions as those used for standard analyses. Any alterations of analytical conditions must be allowable under the method requirements. All sample data must be processed by the same procedures as those used for processing standard data. Any discrepancies must be documented
Sample not analyzed at appropriate level or not reported at correct	**Overdilution of Samples or Misrepresentation of Detection Limits –** Intentionally diluting a sample to such and extent that no analytes (target or non-target) are	Dilutions must be made on a reasonable basis, such as high concentrations of target or non-target analytes, matrix interferences, oily samples, and other components in the sample that could harm the

Problem	Unacceptable Solution	Acceptable Solution
detection limit	detected without justification as to why the high dilution was made. Reporting a detection limit that does not represent the sample analysis (e.g., not including dilution factor in sample detection limit)	instrument. Include details on the reason for the dilution in a case narrative. Sample detection or reporting limits must include and dilution factors.
Non-compliant data	**Deletion of Non-Compliant Data –** Intentional deletion or non-recording of non-compliant data to conceal the fact that analyses were non-compliant.	All data associated with sample collection and analysis, including any out of control events or non-compliant data, must be documented and retained. Preventive/ corrective action must be taken and documented for any non-compliant data.
Undesirable situation with analysis or sample; knowledge of unethical conduct	Concealment of a Known Problem – Concealing a known analytical or sample problem from laboratory management and/or client. Concealing a known unethical behavior or action from laboratory or corporate management.	Any knowledge of analytical or sample problems must be communicated to laboratory management and the client. Any knowledge of unethical behavior or actions must be fully communicated to laboratory or corporate management.

Environmental Quality System Development within the University Structure

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Abstract - There is significant progress in Environmental Quality Systems development, especially with the completion of NELAC Standards. While contemporary Quality Systems concepts are designed primarily for the commercial environmental laboratories, there is a growing demand for comprehensive Quality Assurance Programs (QAP) for academia-based environmental centers conducting research supported by the extensive analytical operation. Using CEMRC and commercial environmental laboratories experience, this presentation will provide a description of key elements and peculiarities of QAP for the university-based environmental operation, as well as challenges faced in QAPs development and implementation process. In order to meet specific research/project requirements university-based environmental centers regularly foster new technology development and analytical methodologies modification and improvement, generating technically defensible analytical data, as well. These factors ideally position them as the models for Performance Based Measurement Systems (PBMS) principles development and application. This presentation will discuss the essential elements of PBMS and outline the ways of successful PBMS implementation in the university environment.

Contemporary Quality Systems concepts are designed primarily for the commercial environmental laboratories, but there is a growing demand for comprehensive Quality Assurance Programs (QAP) for academia-based environmental centers combining research with the extensive analytical operation. Currently working as QA Manager for New Mexico State University based environmental monitoring and research center, I define the major reason of relatively little success of QA Program implementation in the university environment as low compatibility of the university culture and QA Systems, since QA systems require heavy regulation of almost all aspects of the operation. Indeed, QS principles development and especially implementation in the university setting is as rewarding, as challenging.

Table 1 outlines the factors that make the QS targeted for commercial laboratory operations marginally applicable in the university setting.

After establishing successful NELAC compliant QS for the commercial environmental analytical laboratory in Louisiana, I've experienced substantial resistance trying to blindly copy it for university based center. Analysis of the roots of this resistance enabled me to identify the disparities listed in the Table 1. The obviously positive features of the

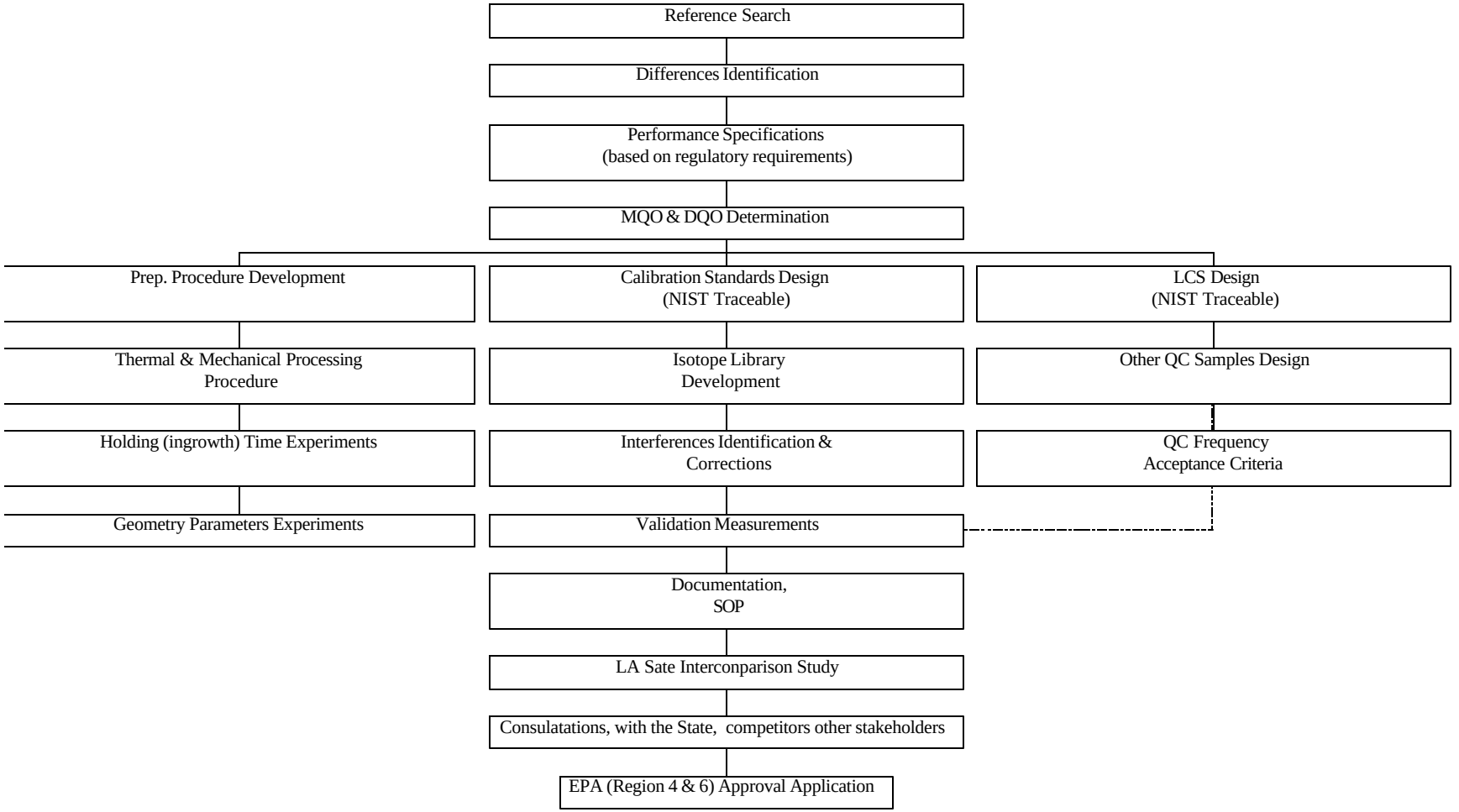
Commercial Environmental Laboratory	University Based Laboratory
Operation completely oriented to the regulatory compliance projects	Research, R&D projects, regulatory compliance not prioritized.
Projects often incur significant legal liabilities	Projects do not incur significant legal liabilities
Prescriptive method practiced when available	Innovative, performance based, sometimes proprietory methods and modifications encouraged, developed and applied
Dominating client-lab relations component	Insignificant (if any) client-lab relations component
Profitability driven operation	Other criteria applied
Highly competitive environment due to the surplus of comparable analytical services.	Grants and projects awards based on the specific capabilities
Solid administrative structure, well defined and maintained chain of command.	Flexible administrative structure and chain of command
Predominance of analytical services, project planning, DQO, sampling performed by others.	Diversified Programs (Field , Environmental IT) with QS not fully integrated in the traditional QS.
Lower level of competency and independence of the middle management (division managers) and staff.	High (often Ph.D.level) qualifications and competency of the middle management (programmatic areas managers) and staff.
Job security driven QA conscience of all personnel	QA conscience should be motivated by other factors. Meanwhile, many employees have deliberately choose the university labs to avoid regulatory pressure.

Table 1. Critical distinctions between the commercial and academia based environmental analytical operation

Condition/impact	Listed in (5)		University Laboratory
Management	Staffing/training needs	More chemists, few technicians	XX
		Technical capability	XX
		More training	XX
	Data Review		X
	Corrective Action		X
	Development Costs		X
Operation	SOP, Documentation, Validation, Demonstration of Capability		X
	Responsibility for Meeting Quality targets		X
	Benefits and Drawbacks	Rewards creativity	XX
		Non-routine	XX
	Changes in Work Mix	Less conventional	XX
		More screening, field testing	X
		Return science to the lab community	XX
Quality System	More Documented Checks, More Often		X
	SOP Preparation/Revision		X
	Method Validation and Verification		XX
	Performance Demonstration		XX
	Method Documentation		X

Table 2. PBMS basic requirements/needs/impacts as listed in (5).
(XX in the last column indicate special advantages)

PBM - Radiochemistry Radium Isotopes in Soil by High Resolution Gamma Spectrometry



university setting turned out to be negative while implementing NELAC- type QS tailored for the commercial operations.

Environmental Radiochemistry field does not have many prescribed methods. This fact long ago triggered our commercial laboratory efforts in the direction of methods development, modification, and validation. But without appropriate regulatory guidelines, the recognition (approval) of developed or modified methods was extremely difficult. Therefore, my perception of PBMS in the recent past was negative and probably typical for the analytical industry (for small laboratories, especially).

This experience, along with the analysis of some recent PBMS-related publications (1 - 6) helped me in realization that the features of the laboratory in the university setting conflicting with the traditional QS pattern form a solid foundation for PBMS-oriented QS. Table 2 illustrates listed in (5) laboratory management, operation and QS necessary conditions (impacts) for successful PBMS development.

Reiterating the information from Tables 1 and 2:

1. University based analytical operations currently have their infrastructure ready for PBMS development and implementation;
2. University based projects may not incur significant legal liabilities.
3. Academia culture organically incorporates PBM needs for non-routine, creative approach; In order to meet specific research/project requirements university-based environmental centers regularly foster new technology development and analytical methodologies modification and improvement, generating technically defensible analytical data, as well.
4. Laboratory capabilities may be expanded due to cooperation with other university departments and facilities;
5. PBM are frequently focused on lower measurement range and detection limits. This will change the project DQO process emphasizing the need to plan the entire sampling, measurement and assessment process up front before any field activities begin (6). The possible scenario for the commercial laboratories often not participating in the project planning, DQO, and sampling activities, is that the collected samples do not meet conditions specified by PBM. As a rule, the university laboratories plan and conduct all phases of the projects, from it's design to results' interpretation.

I would like to share my PBM development and implementation experience in the form of a case study. As I've mentioned in the introduction radiochemical environmental analysis does not have many prescribed procedures, especially for the matrices other than drinking water. Nevertheless, many states regulatory developments of the last decade (Gulf Coast Region, in particular) proscribe and enforce the monitoring for Naturally Occurring Radioactive Materials (NORM), with the stringent limits for ^{226}Ra and ^{228}Ra isotopes in soil. The flow chart presents key activities resulted in the development and implementation of the procedure "Ra Isotopes in Soil by High Resolutiohn Gamma Spectrometry" by Louisiana based commercial laboratory under my supervision.

The sequence of activities on the flow chart is consistent with the NELAC draft of BMS scheme developed much later (2). The last two sections of the chart not reflected in (2) were directed towards

method's recognition and approval by state and federal regulatory agencies for legal defensibility of the analytical data. This long and effort intensive process resulted in successful recognition and approval on the State of Louisiana level due to the collaborative efforts of Louisiana Department of Environmental Quality (currently one of a few NELAC accrediting authorities), local universities, competing laboratories, and other stakeholders. EPA's approval still pending (over six years).

Moving to the university based center, I discovered that the similar pattern is utilized for the this procedure development and validation. But the approval phase is not essential providing that major projects do not incur significant legal liabilities. Therefore, being a substantial drawback for commercial analytical industry's PBMS enthusiasm , present state of PBMS legislative development does not affect the university based facilities' motivation.

Reiterating all the factors mentioned, the environmental analytical facilities are ideally positioned as the models for PBMS principles development and application.

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Development of a Quality Management System in a Small Environmental Testing Laboratory

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Abstract: The Chemistry Quality Assurance Branch provides quality assurance to Army Corps of Engineers environmental projects through split sample analysis. While functioning as a quality assurance facility, the laboratory's internal quality assurance program has strengthened in recent years. The enhancement of the internal QA system enabled the laboratory to more effectively fulfill its operational role as a technical resource for the Army Corps of Engineers.

Incorporation of a more robust quality assurance system into a fully operational laboratory is greeted with a number of different responses. Even with elements of a QA program already present, development of an integrated system required changes in workflow, communications, documentation, and attitudes. Specific tools were developed to initiate and track corrective actions, while minimizing workflow disruptions. Communications were enhanced through development of small teams around primary analytical methods. Group training and informational seminars were also used to build communication throughout the laboratory. Custom logbooks and other forms were created to ensure that documentation was completed with little additional time requirements. Quality assessment tools such as control charts were standardized and provided insights on method performance. A new laboratory information management system was introduced and significantly increased the influence and effectiveness of the QA program. The introduction of process and procedural changes needed to enhance our quality approach to analytical work, in addition to the operational requirements necessary to achieve financial goals, led to changes in the way analysts and management thought about and accomplished their work.

The Chemistry Quality Assurance Branch (CQAB) laboratory has been in a state of flux for the last few years due to re-organizations in the Corps of Engineers. Originally one of seven Division quality assurance laboratories and then known as Missouri River Laboratory, the CQAB is now the only such facility within the Corps. Throughout the organizational changes, the mission of the laboratory has remained the same: to provide chemical analytical services, quality assurance evaluations, and technical assistance directed toward the Corps efforts to provide timely and cost effective technical solutions to environmental problems. In an effort to strengthen the internal quality assurance system, the laboratory added staff who monitored and implemented refinements to the Corps quality assurance (QA) program which have appeared in documents such as EM 200-1-1 (Validation of Analytical Chemistry Laboratories), EM 200-1-6 (Chemical Quality Assurance for HTRW Projects) and the Shell for Analytical Chemistry Requirements.

The Chemistry Quality Assurance Branch is a small laboratory with twenty-six permanent employees, including technical, administrative, and maintenance personnel. The technical staff is highly skilled and has an average experience level of 18 years. The laboratory provides testing by a wide variety of SW-846 and ASTM analytical methods. To document and improve the quality of this work, the CQAB hired a dedicated QA staff in 1996. The technical staff members who had previously overseen the QA program did the work as an additional duty. The new QA staff formalized components of the program that were already in place, added and implemented new components, improved documentation, clarified QA policies and objectives, and provided feedback on QA and QC (quality control) activities throughout the facility. The laboratory now has a fully functional, well-accepted, and management-supported QA system in place.

The initial steps towards improving the quality of the laboratory's work involved customization of corporate Laboratory Quality Management Manual (LQMM) and Standard Operating Procedures (SOPs). The LQMM improved upon previous versions by adding details of the laboratory's philosophy towards quality and the responsibilities of staff towards the quality of their work. Earlier SOPs were short step-by-step descriptions of the methods, and generally lacked important additional information such as safety, calculations, quality assurance, and references. The original documents also tended to omit some of the detailed information necessary for method implementation. The corporate documents were much more complete, had thirteen separate sections, included example log book pages, specified equations for calculations, provided waste disposal instructions, discussed quality control, and indicated steps for data validation. Specific details such as calibration range, spike mixtures, acceptance criteria, and catalog numbers for supplies were added to the corporate documents. New quality control procedures were added to the SOPs, also. For instance, batch laboratory control samples (LCS) for every method now included all the method analytes, and laboratory performance limits were developed from these data. The performance of new method detection limit studies became consistent with 40 CFR Part 136. Standardized procedures were incorporated for evaluation of quality control samples, and corrective actions for out of control events were described. Most of these QA processes occurred regularly before development of the new SOPs, but the documented inclusion of such processes in the SOPs served as a powerful reminder of the need to perform them.

With a permanent QA staff in place, review of data from a QA perspective became routine, but incorporating this additional step into the testing and reporting process disrupted normal workflow. The number of corrective actions increased with QA oversight, as did documentation of such actions. Corrective actions based on review findings were naturally disruptive, and tended to have minimal capability of improving results since the actions occurred significantly after the fact. Re-analysis or re-extraction of a sample with a low surrogate recovery has minimal value if the appropriate corrective action occurs after holding time has expired. More benefit was obtained by inserting a QA review step between completion of the analysis and initiation of data reduction and processing. Deviations from quality control acceptability (calibration verification, method blank contamination, laboratory control sample recoveries, etc.) were evaluated immediately after data acquisition, and appropriate corrective actions were implemented. Peer and QA review of the raw data and reported results also occurred after reports were generated, and corrective actions could also be initiated at that point. The added

timeliness of the corrective actions and the increased attention to the method-specific requirements such as calibration techniques and verifications, tuning criteria, and use of quality control samples led to significant quality enhancements. Despite the benefits of the process, however, some analysts resisted this key change in workflow, and its full implementation across the laboratory was gradual.

Small teams were formed around each major method to share analysis and review duties, improve efficiency, plan throughput, communicate changes, and provide feedback on method performance. Before the formalization of the QA program at the laboratory, back-up analysts were available for most methods, but for the most part, did not stay up to date with daily implementation. Initially the teams met formally on a weekly basis, but most soon substituted more frequent informal discussions to share information. The team approach increased the base of knowledge for each method, which was especially important due to the limited number of technical staff. As a member of a team, the primary analyst was required to verbally communicate information about the test method and results to other team members. As a consequence, improved response skills have been observed during internal and external audits.

The most important aspect of the team approach was the development of additional peer review capability. Previously, for some methods, expertise was restricted to a single analyst. While many analysts understood other methods in a general way, their ability to expertly evaluate raw data from another method was limited. Without method-specific expertise, peer review of data was mostly a check of the completeness and correctness of report headings. The transposition of results from raw data printouts to the report could be checked for correctness, but the ability to verify the correctness of raw data was minimal. Peer reviewers were included as team members and given training by the primary analyst on evaluating and reducing raw method data. In some instances, peer reviewers developed facility with the analytical software for the new method and were able to serve as back-up to the primary analyst for results reporting. Efficiency and quality were improved through a single process. The capability for data review at the peer level at the laboratory increased such that for some methods, four different individuals are now able to accomplish detailed technical review of raw data.

The documentation requirements of an enhanced QA program were another change to routine procedures. Custom pre-printed logbooks were developed for most areas; the pre-printed forms provided prompts for record keeping and were especially useful in preparation areas that tend to have high turnover. Examples of completed forms were included in SOPs to inform users of appropriate documentation practices.

Other than for the input on SOPs, the influence of the QA program on laboratory work was most strongly felt through standardization of custom method report generators. Installation of an Oracle-based Seedpak laboratory information management system (LIMS) led to tremendous change as the reporting for most laboratory testing became automated. Development of customized automatic report generators created the opportunity for development of uniform reporting protocols. Reports for many test methods were created manually before use of the Seedpak LIMS, and different formats were used for reporting by different analysts. With the onset of laboratory-wide automatic report generators, flagging conventions, significant figures, use of quality control samples, and many other aspects of

technical data reporting were standardized. When manual reporting was the norm at the laboratory, batches for some methods included LCS and LCS duplicates, while other methods used matrix spikes and matrix spike duplicates to demonstrate reproducibility. For some methods, real world samples were used as control samples to demonstrate analyte recovery performance, while for other methods, the control samples were blank spikes. Some methods flagged blank contamination; others did not. Results were reported down to the method detection limit for some methods, but not below a quantitation limit for others. For some tests, the term laboratory reporting limit was used to identify the quantitation limit while for others the term was used to describe the method detection limit as identified in the Federal Register. Other inconsistencies were also observed. Consistent across all methods was the potential for typographical errors.

Coordination between the CQAB QA Officer, analyst, and Information Management staff during the development of the automated report generators allowed consistent reporting practices to be incorporated across the laboratory. The use of standardized reporting practices led to efficient development of the report generators for the various methods, and also served to standardize the QA program across the laboratory. For example, requirements for batch quality control samples were standardized so that all batches, regardless of test method, included a method blank, LCS, laboratory duplicate, matrix spike, and matrix spike duplicate, if possible. For all test methods, results were reported between the laboratory reporting limit (quantitation limit) and method detection limit. Blank contamination and estimated concentrations were flagged. What had previously been a method-specific approach to quality assurance and quality control became a laboratory-wide program through installation of a new LIMS.

The laboratory-wide approach to quality at the CQAB was strongly promoted by the QA staff and laboratory management, and is now fully accepted by the technical staff. Analysts are evaluating work more critically, initiating corrective actions, thoroughly documenting their work, considering the usability of results for the customer, and demonstrating the performance of testing methods. Traceability is excellent in most areas. Compliance with method and program requirements is observed reliably across the laboratory. Results reports are reviewed at four separate levels lending increased confidence in the validity of reported data. The review processes ensure that the data are technically correct and that they were generated in a manner to support the usability by the customer. Technical staff is frequently involved with planning for large projects, and help to define data quality objectives and select appropriate test methods for projects. Continual improvement of quality leading to technical success has become the norm.

QA Growing Pains:

A State Perspective on Implementing an Organizational-wide Quality System in Environmental Laboratories

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Abstract - To implement an effective and efficient quality system in a network of established environmental testing laboratories requires a committed long-term effort that is potentially fraught with multiple obstacles. The presentation discusses one state's ongoing efforts at implementing such a system.

First is the need to convince management of the rational for a quality systems-based approach verse the traditional QA/QC program. Once development of a quality system has been sanctioned, a team-based approach utilizing project planning tools is a good way to approach the effort. Resources are assigned to the development of key quality system components and generally a phased-deployment or roll-out works best. Once implementation is underway assuring operational utilization and compliance with the quality system is a vital step in the process. Important to successful implementation is ongoing assessment and refinement of the quality system.

Fundamental and key elements of the laboratory quality system are numerous and need to work in concert with each other. Quality system elements to be discussed in the presentation range from management and QA roles and functions to the typical documentation of laboratory policies and procedures. Further, numerous QA assessment tools and other vital quality system practices that play an important role in making a complete quality system will also be mentioned. In addition, efforts must be undertaken to integrate the laboratory quality system with other management systems within the organization.

The bottom line is that all environmental laboratories need a quality system more now than ever. Data users need it. Customers' expectations for data quality are high. USEPA policy and/or programs call for it. Additionally, a good quality systems can benefit the organization in multiple ways and help avoid the "pay-me-now or pay-me-latter" syndrome. In conclusion, all environmental testing laboratories (i.e., academic, private, commercial and especially governmental) need to invest in and implement a quality system based on a recognized standard (e.g., NELAC, ISO 17025, ANSI/ASQC E-4). This paper recommends pursuing NELAP laboratory accreditation with a NELAP-recognized accrediting authority.

A COMMITTED JOURNEY OVER TIME AND OBSTACLES

Early Efforts: In the early part of the 1990's the Division of Laboratories's Quality Assurance Committee (QAC) began to evaluate and reconsider the Division's then quality assurance program which was founded on and compliant with the USEPA's drinking water laboratory certification program, approved test method quality control requirements and quality assurance program plan guidance. What the QAC recognized was that while the division's present quality assurance program met the above USEPA requirements and promoted the production of quality data, it did have specific shortcomings in documenting some established quality assurance activities. Additionally the QAC felt the Division needed to have practices and procedures established for some recognized key quality assurance activities. As an outcome of this evaluation the QAC made a presentation to laboratory management on the need to expand the present quality assurance program so as to adopt more of a quality systems-based approach toward its quality assurance program. At that time, the Division of Laboratories represented a network of five environmental laboratory facilities performing, organic, inorganic, microbiological and toxicity testing for the Illinois EPA's regulatory programs.

What the QAC actually presented was a plan for documenting via standard operating procedures (SOPs) already established good laboratory practices (e.g., sample receipt and handling, laboratory water quality checks, analytical balance calibrations and checks, documenting test methods) and to formalize or implement what the QAC considered to be needed and very beneficial quality assurance practices (e.g., corrective action, data review/validation, internal audits, control charting). Over the next few years multiple division-wide SOPs were written, approved and implemented. As with all new quality initiatives it took time for the organizational culture to adjust to these changes and to also start seeing the actual day-to-day benefits that can be derived from these new quality assurance practices. Some initial resistance to the plan came about due to the fact that the USEPA was not requiring these quality assurance practices at that time. It was a typical example of having a quality assurance program that meet the established USEPA QA/QC requirements of the day and no more. Subsequently, once implementation of these initial efforts were completed, the QAC felt that at least the shortcomings identified earlier in the quality assurance program had now finally been addressed.

NELAC's Impact: Next the QAC began to examine developing a comprehensive and efficient quality system for the Division based on ISO Guide 25 and the QAC's collective base experiences. At roughly the same time, December 1994, the draft NELAC Quality Systems standards were released in a Federal Register Notice and then quickly evaluated by the QAC.

The QAC with the advent of the new draft NELAC quality systems document saw an opportunity to help further convince laboratory management and key staff that the traditional approach to regulatory quality assurance programs not only should change but was indeed going to change. That message delivered was that the USEPA, States and other stakeholders were preparing to develop and eventually utilize a more comprehensive quality systems-based approach to laboratory quality assurance and that the Division should take a proactive posture toward this new initiative. Since the new NELAC initiative appeared to have support from within the USEPA, some states and especially the environmental laboratory community, it was relatively easy to convince laboratory management that

NELAC would eventually have a broad impact on the Division and that it should be further evaluated for possible Division-wide action. However the actual task of identifying and planning what needed to be done to begin to address this new quality systems standard, finding the resources needed to do it, gaining the needed level of support and ongoing commitment for this major undertaking was not without negotiations, struggles, compromise and old fashion role-up your sleeve's effort on the part of many stakeholders. This early efforts to bring focus on NELAC was even harder since the benefits that NELAC would bring verse what some viewed as unnecessary, counterproductive additional QA was not initially seen or understood by all those involved.

In early 1995 the QAC, with management support, formed a Division-wide continuous quality improvement team, consisting of both management and laboratory staff, to develop plans to bring the Division into full compliance with the NELAC Quality Systems standards and the USEPA's Good Automated Laboratory Practices (GALP). The team employed a typical project management approach (e.g., gant charts) and utilized various continuous quality improvement tools (e.g., nominal group technique) to accomplish its mission. The team first developed an overall strategic plan for the effort and presented that plan to the entire management team for review and approval. A significant first task in the strategic plan was to perform an assessment of the Division against the then draft NELAC Quality Systems standards and the EPA's GALP document. With the completion of the assessment process various tactical/operational plans needed for the laboratories and the QA staff were then developed. These plans described the specific tasks, time-lines, plan milestones, responsible individuals or groups and other resources required to bring about eventual full compliance with the NELAC Quality Systems and GALP documents. The tactical/operational tasks in the plans were prioritized and structured to allow for implementation to occur in a logical and phased roll-out.

One critical step toward assuring success of the tactical/operational plans was initially providing management with accurate and timely information on the amount of staff time and resources that would be needed to accomplish the tactical/operational plans laid out for the effort. This allowed management to budget for and adjust the Division's primary workload (e.g., testing) so staff time would be available to work on their assigned tasks under the plan. Changes in the demand for staff time and resource have been routinely monitored (i.e., monthly or quarterly), evaluated and reported on during the plans' life.

As the plan was rolled-out another critical activity that helped assure that the quality system being developed and implemented was indeed effective and also being complied with were the frequent utilization of assessments (i.e., audits) by the QAC. These independent assessments helped assure proper and complete operational utilization and compliance with the Quality System elements that had been approved and put in place. The assessments also provided management with frequent and accurate pictures of where each laboratory and the entire Division stood in regards to the tactical/operational plans and how efficient and effective new quality system practices were during their initial utilization. Some major and minor refinements to quality system practices were brought about due to these frequent assessments.

Lastly, a key activity in making this effort a success were ongoing reviews and a formalized reporting process that monitored the overall plans and the progress of each active task. Again, the critical step

and activities just discussed played a significant role in helping the agreed to plans move forward and toward holding individuals and groups accountable for the plans' success.

The tactical/operational efforts underway in the Division to bring about full compliance with the NELAC Quality System standards and GALP are now into their fifth and now final year. The effort has been recognized as an ongoing Division-wide strategic goal for the organization and consequently the focus of considerable management and staff time over the past five years. I think it worthy to note that multiple hats were worn by many people during this entire time frame, resources were stretched thin, yet eventually a new appreciation for the critical role that a comprehensive and documented quality system has in laboratory operations has been ingrained in both the Division's and our customers' cultures.

What faces this Division now, as it does any organization at the same point we are, is the ongoing challenge of improving the Quality System that has now been developed and maintaining a firm commitment at all levels to the quality systems-based approach as permanent cornerstone to our laboratories' operations.

THE QUALITY SYSTEM

The Division's resulting Quality System can best be summarized and presented by identifying the fundamental and critical elements in that system and by listing the Division-wide policies, standards operating procedures and manuals that document that system. All these elements should be defined and documented via policies, procedures or manuals.

Fundamental and Critical Elements in a Laboratory Quality System

1. Management and staff quality assurance roles and responsibility
2. Quality assurance policy statement
3. Quality assurance oversight and monitoring function
4. Quality assurance planning and reporting to management
5. Training (e.g., quality systems, ethics and fraud prevention, demonstration of capability)
6. Group and individual staff understanding and compliance with the quality system
7. Policies and standard operating procedures (e.g., test methods, good laboratory practices, quality manual)
8. Facilities and equipment maintenance
9. Calibration practices and procedures
10. Quality control schemes
11. Data review and reporting
12. Sampling handling and tracking (e.g., evidentiary chain-of-custody)
13. Review, maintain and control records (e.g., document control, laboratory notebooks)
14. Good automated laboratory practices (GALP)
15. Assessments (e.g., TSAs, MSRs, PT, DQAs)
16. Corrective Action

17. Vendor and supplier quality (e.g., supplies and subcontracting)
18. Resolution of customer complaints
19. Continuous quality improvement

The way the Division has over the development of our Quality Systems translated the above elements into our Quality System have been mainly through implementing the following policies, procedures and manuals. However, numerous presentations, small meetings, and one-on-one discussions have been needed to help facilitate acceptance and utilization of these policies, procedures and manuals. Please note, that we have learned, that the quality of these documents is critical to accomplishing the goals and mission of the quality system.

Division-wide Policies and SOPs

1. Initiation, Draft, Approval, Distribution and Revision of Standard Operating Procedures
2. Sample Receipt, Log-in and Storage
3. Corrective Action
4. Document Control
5. Data Validation
6. Control Charts
7. Logbook Maintenance, Utilization and Review
8. D.I. Water Quality Assurance
9. Significant Figures and Rounding
10. Balance Calibration and Checks
11. Thermometer Calibration
12. Oven and Refrigerator Temperature Checks
13. Resolution of Complaints
14. Internal Records Storage and Retrieval for Laboratory Records
15. External Records Storage and Retrieval for Laboratory Records
16. Internal Audits
17. Calibration of Manual Volumetric Dispensing Apparatus
18. Use of the LIMS Training Log
19. Logging a Sample Into LIMS
20. Scheduling and Updating Sample Status in LIMS
21. Manual Data Entry Into LIMS
22. Exceptionally Permitting Departures from Documented Policies, Procedures, or Standards
23. Handling, Analysis and Reporting of Proficiency Testing Samples
24. Obtaining Representative Samples and Subsamples
25. Purchasing, Receipt and Storage of Laboratory Supplies
26. Sample Acceptance Policy
27. New Work
28. Management System Reviews
29. Sample Disposal
30. Policy and Program Requirements for the Ethics and Data Integrity Program

31. Ethical Laboratory Practices for the Analysis of Samples and Quality Control Data
32. Guidelines for the Reporting of Unethical Behaviors and Actions

Division-wide Manuals

33. Division of Laboratories' Quality Management Plan
34. Division of Laboratories' Strategic Quality Planning Manual

Integration of the laboratory's Quality System with other management systems (e.g., Agency Quality Management System, Personnel, Ethics, Strategic Quality Planning, Training, PBMS): The foundation for the Division's quality system elements are from a integration (i.e., blend) of ISO Guide 25, NELAC Quality Systems, and the ANSI/ASQC E-4 (i.e., the EPA's QA/R-2 document) standards. This success of the above described quality system relies heavily on QAC, management, and staff involvement in every aspect of its operation. However, the success of the Division's quality system also relies on an integration of the quality system with other management systems.

A quality system must have means to integrate and interface with other systems and activities. Our quality systems does at times interfaces with various elements of the personnel system. However we have found that the barrier between the quality system and specific kinds of personnel actions needs to be carefully understood and managed. It interfaces with the procurement process regarding purchase of laboratory supplies and commodities. It routinely, as everyone is keenly aware, interfaces on a day-to-day basis with laboratory operations and any subcontracting of laboratory services. The Division's quality system interacts with the Agency's and the Division's training systems that are in place, specifically for quality systems and ethics related training. Further, the quality system and its needs are considered and have input into our annual strategic quality planning efforts. The quality system should directly or indirectly support and benefit the organization's mission and most if not all the organization's strategic goals. Lastly, quality system activities planned for are taken into consideration during the Division's annual budget and workload planning efforts. It is absolutely critical for management to factor in the annual QA workload and resource needs into the future budget and the laboratory's projected workload.

We have seen that the more these above interactions are defined or formalized the more our organization realizes the value its quality system has and how it positively interacts with or supports other key systems or processes. Our Division is still working on refining and formalizing some of the above relationships. Again, it cannot be overstated, what positive impact that the ongoing relationships between the quality system, people, other Division systems, Divisional strategy and the Division's customers has had on our organization.

As a special note - One new system being introduced to many environmental laboratories via the various EPA program offices is the performance-based measurement system (PBMS). This author and many other NELAC and PBMS stakeholder feel that a integration and close reliance between PBMS and the laboratory's quality system is critical to the success of PBMS in the laboratory. In fact many

feel PBMS should not occur within a laboratory unless a complete and effective quality system is in place and accredited. In fact, it is this author's view that all environmental laboratories need an accredited quality system now more that ever.

WHY A QUALITY SYSTEM NOW MORE THAN EVER

It is becoming increasingly evident not only within this Division, but to all that follow developments impacting the environmental testing community, that information data quality and laboratory data quality are moving more to the forefront of issues facing the entire environmental sector. We all read about laboratory data quality related issues almost every day in publications, and in EPA's Inspector General and Government Accounting Office reports. What motivates our Division's efforts at developing, implementing, and especially maintaining a comprehensive quality system are the following assumptions or realities:

- Data users (especially regulatory agencies) need information of a defined level of quality to make good decisions;
- Customer expectations for data quality are raising (even if they still want lower testing costs and faster turn-around-times, data quality is no longer viewed as a given commodity obtained by just following mandated test methods);
- Helps avoid the Pay-Me-Now ($) or Pay-Me-Later ($$$$$) syndrome (otherwise know as the "See I told you so" comment occasionally made by QA staff to laboratory management);
- USEPA QA policy and/or programs require it (e.g., ANSI/ASQC E-4, 1994), and;
- It really works and can benefit the organization in multiple ways (e.g., a system for problem prevention, detection, correction and/or resolution).

Advise to all environmental laboratories (i.e., governmental, academic, private and commercial) invest in and implement a Quality System which is based on a standard or an integration of the following standards:

- NELAC Quality Systems**;**
- ISO 17025, and/or;
- ANSI/ASQC E-2000.

Don't place your organization or its customers at greater risk or potential liability by not having a comprehensive, efficient and effective quality system in place or having one that is not completely documented. Develop a quality system that you know supports your organizations' mission and goals.

NELAP laboratory accreditation is making the quality systems efforts at all laboratories a level playing field. Don't be caught on the sidelines asking yourself why you did not develop sooner or already have

implemented such a quality system on the day your laboratory gets publically scrutinized for data quality problems (that are eventually linked to failures or shortcomings in your quality system or its effective implementation) or even worse faces being shutdown.

Pursue NELAP laboratory accreditation with a NELAP-recognized accrediting authority!

In conclusion, the benefits our organization has repeatedly seen since the implementation of our quality system have far out weighed the initial resource drains and organizational stress that occurred during the development of that system. Today, we feel our quality system is a key factor in our Division's effort to position ourselves to successfully meet the short and long term needs of our Agency and to untimely better serve the taxpayers that support our work. With the examples and case history presented in this paper, I can only hope it further encourages environmental laboratories that have yet to do so (especially governmental laboratories) to pursue NELAP laboratory accreditation with a NELAP-recognized accrediting authority.

Quote of the Day:

"The pursuit of quality, per se, is no virtue; the pursuit of quality for customer loyalty, and an efficient organization is no vice."

Quality Science and Quality Assurance: Observations of a Career Environmental Scientist Who is Now a QAM

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The purpose of this talk is to examine the relationship between quality science (QS) and quality assurance (QA). The generally accepted definition of QS is data that are published in the peer-reviewed literature. The quality of the data is assumed by the general scientific population to be directly proportional to the status of the journal. For example, it is highly prestigious to have an article published in *Science*. First authors on an EPA-sponsored manuscript are expected to have the paper reviewed by the coauthors (they should also review the data), and then the manuscript should be reviewed by at least two scientists, one of who must be from outside the authors' division. After this review and approval, the manuscript is sent to a peer-reviewed journal where it is reviewed by several anonymous scientists. After the comments of the reviewers are addressed, the manuscript can either be accepted or rejected for publication by the journal. Few reviewers ever analyze the raw data in the laboratory notebooks nor were they in the laboratory where the research was conducted to observe quality control measures on instruments (e.g., temperatures in incubators) or how the samples were stored and labeled. The generally accepted definition of QA is the guarantee from an audit team that the entire study was adequately and correctly conducted and recorded according to the study protocol. The data from such an audited study are therefore accurate, are defensible in a court of law, and are reproducible. A QA audit will review all aspects of the study including data files (notebooks, protocols), as well as equipment, sample storage, actual experimental organisms (animals or cells) and records management and storage. Therefore, data that have undergone a QA audit are more closely inspected that data in the peer-reviewed literature. QA audits assist EPA Scientists conducting their studies by identifying both excellent study records an d study deficiencies, and thereby produce higher quality scientific data. In the opinion of this EPA Scientist and QAM, the relationship between QS and QA can be compared to automobiles and gas. One helps the other function and they are much stronger together than alone. (This abstract does not necessarily reflect EPA policy.)

Verifying Data – EQuE

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Abstract – As a part of the overall plan to emphasize data quality and data usability, the Florida Department of Environmental Protection is developing new software that will enable the user to review data for completeness, data quality elements, and compliance. This software, EQuE, short for Environmental Quality Evaluator, will be available to Department programs to assess data for quality assurance and compliance problems. The demonstration of EQuE will highlight the flexibility and use of the software for many Department programs.

At the 1999 Quality Assurance Division Conference, the Florida Department of Environmental Protection presented their ideas on monitoring data quality within the State. This included requiring the use of laboratories accredited under the NELAC standards, more emphasis on the data quality objective planning process, and a strong commitment to reviewing more data more consistently and with greater efficiency.

The software, EQuE, (Environmental Quality Evaluator) is being developed specifically for the purpose of assessing large amounts of data quickly and efficiently. Some of the planned features include

1. Using electronically submitted data sets;
2. Identifying quality control problems reported by the laboratory;
3. Assessing the quality of the data based on the information required by the program;
4. Summarizing the findings;
5. Providing a suggested course of action to be taken with specific findings; and
6. Identifying compliance exceedances.

The Department programs have different needs, quality assurance requirements and reporting specifications. In order to meet these diverse program requirements, EQuE is being designed with a great deal of flexibility. The software demonstration is based on the model designed for groundwater monitoring reports, but can be easily configured for other types of data.

One of the Department programs is currently testing EQuE. While designed for internal use, the final software product will also be offered to laboratories and laboratory clients for use in evaluating data before submission.

Widespread acceptance of EQuE will also pave the way for electronic data submission and eliminate many of the transposition and data entry errors that are inherent in the current system of data reporting.

ISO/IEC 17025 and PBMS

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Abstract — The new international requirement for laboratory competence, ISO/IEC Standard 17025, contains a section (5.4) which discusses how laboratories should implement and use laboratory test methods. This section, which does not exist in ISO/IEC Guide 25, provides the basic framework for implementing a Performance Based Measurement System (PBMS). This presentation will summarize the requirements for laboratory test methods as set forth in ISO/IEC Standard 17025 as they relate to environmental measurements, and compare these requirements to the guidance established by the U. S. Environmental Protection Agency (USEPA) for implementing PBMS.

INTRODUCTION

The Quality System requirements for laboratories to become accredited under the program developed by the National Environmental Laboratory Accreditation Conference (NELAC) are currently based on an international guidance document, ISO/IEC Guide 25. The NELAC Quality Systems committee has indicated that Chapter 5 of the NELAC Standards will be rewritten to conform to the new requirements for laboratory competence, ISO/IEC Standard 17025. ISO/IEC 17025 defines the requirements that laboratories must meet if they "wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results." Thus ISO/IEC 17025 will be used internationally as the basis for granting (or denying) accreditation. If NELAC adopts the framework provided in Section 5.4 of ISO/IEC 17025, a Performance Based Measurement System (PBMS) approach for performing environmental analyses will become a reality for the laboratory community.

One of the barriers to implementing PBMS has been the current system of laboratory accreditation which focuses on conformance to details published in an EPA approved method. Accreditation is a necessary component under PBMS, as some laboratories may abuse the freedom without the check that an accreditation program provides, and accreditation provides the professional standards of performance essential for ensuring legal standing (ELAB).

Under the current NELAC Standards, a laboratory is responsible for documenting how it performs a method in a Standard Operating Procedure (SOP), for demonstrating its proficiency with the method (according to a protocol established in Appendix C of Chapter 5 of the NELAC Standards), and for documenting the quality of data obtained by analyzing the appropriate types of quality control samples. Further, method requirements are one of only 13 key requirements that a laboratory must meet to

become accredited under the NELAC program. Thus, laboratory auditing under NELAC has already taken a major step towards approving laboratories without focusing on the specific details in EPA-approved methods.

Although the NELAC Standards could be used today for approval of new procedures implemented by a laboratory, the current version of the NELAC Standards does not adequately address this topic. For example, as described in Appendix C of Chapter 5 of the NELAC Standards, all a laboratory would need to do to demonstrate its competence with a method would be to analyze four replicate spike blank samples at a concentration of 10 times the detection level. This approach is inadequate to verify that a method has been implemented correctly (GIES).

ISO/IEC Standard 17025 contains many of the elements which are key to a successful PBMS, including requirements to:

- technically justify method changes (Section 5.4.1);
- notify client's of method changes (Section 5.4.1);
- confirm that the laboratory can properly use any method (Section 5.4.2); and
- validate methods appropriately before use (Section 5.4.5).

General Requirements (ISO/IEC 17025–Section 5.4.1)

Section 5.4.1 provides the general requirements for using any method, an EPA promulgated method, a method published by another organization such as ASTM, or an internally developed laboratory method. This section indicates laboratories should use methods which "meet the needs of the client and which are appropriate." This language provides a laboratory with unlimited flexibility to use any method, so long as this basic principle is met. The ISO/IEC requirement is consistent with EPA's stated goals for PBMS—**"**Where PBMS is implemented, the regulated community would be able to select any appropriate analytical test method for use in complying with EPA's regulations (*62 FR 52098*)."

This section also indicates that deviations from published methods can occur, but only if "the deviation has been documented, technically justified, authorized, and accepted by the client." The requirement to document a "deviation" is consistent with the existing language in Section 5.10 of the NELAC Standards and is also consistent with good laboratory practice (Mealy). Note that the EPA language above provides the "regulated community," not laboratories, with the flexibility, consistent with the ISO/IEC language which requires laboratory customers to accept modifications to methods.

Finally, this section notes that published methods do not need to be rewritten as a laboratory SOPs if the methods have been written "in a way that they can be used as published by the operating staff of a laboratory." This language is consistent with the existing language in Section 5.10.1.2 of the NELAC Standards and is appropriate to allow laboratories to use methods developed by others without having to rewrite the method in a particular format.

Method Selection (ISO/IEC 17025–Section 5.4.2)

Section 5.4.2 describes the selection of methods and indicates that published standardized methods are preferred, but that these methods, when necessary, "shall be supplemented with additional details to ensure consistent application." The use of standardized methods provides many advantages and most laboratories do use such methods. ISO/IEC 17025 indicates such methods are preferred, but allows laboratories the ability to use these standard methods as the genesis for the laboratory's SOP, and does not indicate that the methods must be followed explicitly.

This section also allows for the use of non-standard methods, indicating that other methods, including methods published in the literature, by equipment manufacturers or those developed by a laboratory, "may be used if they are appropriate for the intended use and if they are validated." Thus, if a non-standard method is used, the laboratory is responsible for performing a method validation study, described in Section 5.4.5 of ISO/IEC 17025. The goal of the validation is to determine if the method is appropriate for its intended use.

Most importantly, Section 5.4.2 requires a laboratory to "confirm that it can properly operate standard methods before introducing the tests." This activity, which is not further discussed in ISO/IEC 17025, is defined as the activities performed by a laboratory to demonstrate competence with a validated method (MacDowell). Appendix C of Chapter 5 of the NELAC Standards has attempted to address this issue, but is lacking for two reasons. First, the activities performed (4 replicate measurements at one concentration) are inadequate to truly verify the method's performance. Second, and most importantly, the results of the NELAC required analyses are compared to arbitrary objectives (e.g., the performance of another method) and not to the customers data needs.

An example of the problem with comparing the results a laboratory obtains to those published in a method, and not to a customer's needs, can be found in a very recent EPA regulation, the new NPDES regulations for hazardous waste incinerators finalized in January of this year (*65 FR 4360*). In this rule, EPA indicated that the monthly average discharge for alpha-terpineol could not exceed 16 ug/L. To demonstrate compliance, laboratories must use Method 625 (or 1625) and document that they achieved a detection level of 20 ug/L and a recovery of 46-163% from the analysis of four spiked samples. The regulated level for benzoic acid in this rule is 71 ug/L. The method required accuracy limits are ns-ns (for no specification); EPA's validation data indicate that recoveries from 0-650% would be expected for this analyte. While the method requirements can likely be met, it is doubtful that achieving these requirements will meet the needs of an NPDES discharger, or be appropriate.

Use of Non-Standard Methods (ISO/IEC 17025–Section 5.4.4)

Section 5.4.4 discusses the use of "Non-Standard Methods" and states "These shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use... and should contain at least the following information:

- Appropriate identification
- Scope
- Description of the type of item to be tested or calibrated;
- Parameters or quantities and ranges to be determined;
- Apparatus and equipment, including technical performance requirements;
- Environmental conditions required and any stabilization period needed;
- Description of the procedure, including
  - handling, transporting, storing and preparation of items,
  - checks to be made before the work is started
  - checks that the equipment is working properly and calibration of the equipment before use
  - the method of recording the observations and results
  - any safety measures to be observed;
- Criteria and/or requirements for approval/rejection;
- Data to be recorded and method of analysis and presentation;
- Uncertainty or procedure for estimating uncertainty."

This section reinforces the requirements to validate methods and obtain client acceptance. More importantly, the section sets forth the information which should be contained in methods. A comparison of the ISO/IEC requirements to those in the NELAC Standards and those established by EPA is presented in Table 1. A review of this information indicates that virtually all of the ISO/IEC elements are contained in either the NELAC or EPA method requirements.

The most significant language in Section 5.4.4 is the requirement for clients to clearly specify the "requirements and the purpose of the test." As discussed in the NPDES example, all too often, method requirements are used instead of the actual data need. This is perhaps the single largest barrier to an effective implementation of PBMS. The existing system of relying on promulgated EPA methods allows regulated entities to demonstrate compliance by indicating that the EPA approved method was used, regardless of the data quality obtained. PBMS may increased the burden on regulated entities as regulatory compliance many times cannot be demonstrated solely by method compliance. Regulated entities will be able to operate under a PBMS framework only if EPA and other regulators establish the compliance standards clearly and only if the regulated community is capable of implementing measurement approaches which can demonstrate compliance.

Method Validation (ISO/IEC 17025–Section 5.4.5)

Section 5.4.5 describes the method validation process, defining validation as "the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled." Note the emphasis on the intended use of the method. In most cases, existing EPA methods have been published for general use, to allow others to determine if the method may be suitable for a given application (USEPA). Thus, for most laboratories using EPA published methods, the validation data published in the method may or may not be suitable for verifying that "requirements for a specific intended use" have been met. In such case, the laboratory who uses the method may need to perform this validation activity, even for well-established, standardized methods (Robertson).

Section 5.4.5.2 expands upon the concept of using standardized methods outside their intended scope, or using modifications to such methods, stating "The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended range and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use." Clearly, the intent of ISO/IEC 17025 is for laboratories to verify that a method is appropriate, consistent with EPA's statement that "the regulated community would be required to demonstrate that the measurement method to be used meets the specified performance criteria by documenting both initial and continuing method performance according to a required protocol (*62 FR 52098*)."

EPA has not provided any clear guidance as to what this demonstration of method performance should entail. ISO/IEC 17025 provides some general guidance indicating that the method validation:

- may include procedures for sampling, handling, and transportation;
- should use one of the following techniques:
  - comparison to reference materials,
  - comparison to results achieved with other methods,
  - systematic assessment of factors influencing the result, or
  - assessment of the uncertainty based on scientific understanding of the theoretical principles of the method and practical experience; and
- should be redone if changes in the method are made.

Summary

ISO/IEC 17025 provides a good framework for implementing PBMS, by providing the requirements laboratories must perform to select and validate methods. More EPA guidance, or a revision to the NELAC standards, is needed on what a laboratory must do to document and demonstrate that a measurement system provides data consistent with its intended purpose in order to fulfill the requirements for method validation in Section 5.4.5 of the ISO/IEC standard.

Table 1. Comparison of Information Required for Methods

ISO/IEC 17025	NELAC, Section 5.10.1.2	EPA*
Appropriate identification	1) identification of the test method	Title
NR	2) applicable matrix or matrices	1.0 Scope and Application
NR	3) method detection limit	1.0 Scope and Application
Scope Item to be tested Parameters and ranges to be determined	4) scope and application, including components to be analyzed	1.0 Scope and Application
NR	5) summary of the test method	2.0 Summary of Method
NR	6) definitions	3.0 Definitions
NR	7) interferences	4.0 Interferences
Safety measures	8) safety	5.0 Safety
Apparatus and equipment	9) equipment and supplies	6.0 Equipment and Supplies
NR	10) reagents and standards	7.0 Reagents and Standards
Handling, transporting, storing and preparation of items	11) sample collection, preservation, shipment and storage	8.0 Sample Collection, Preservation, and Storage
Uncertainty or procedure for estimating uncertainty	12) quality control	9.0 Quality Control
Checks to be made before the work is started Calibration of the equipment	13) calibration and standardization	10.0 Calibration and Standardization
Description of the procedure	14) procedure	11.0 Procedure
Data to be recorded Observations and results	15) calculations	12.0 Data Analysis and Calculations
NR	16) method performance	13.0 Method Performance
NR	17) pollution prevention	14.0 Pollution Prevention
Criteria and/or requirements for approval/rejection	18) data assessment and acceptance criteria for quality control measures	9.0 Quality Control
NR	19) corrective actions for out-of-control data	9.0 Quality Control
NR	20) contingencies for handling out-of-control or unacceptable data	9.0 Quality Control
NR	21) waste management	15.0 Waste Management
NR	22) references	16.0 References
NR	23) tables, diagrams, flowcharts and validation data	17.0 Tables, Diagrams, Flowcharts, and Validation Data
Environmental conditions required	NR	NR

* Environmental Monitoring Management Council; Format for Analytical Methods

NR No Requirement

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Tracking Trends on Proficiency Testing Studies – A Helpful Tool for Assessing and Improving Data Quality

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This paper provides a procedure for tracking trends on proficiency testing (PT) studies using commonly available software. By evaluating results for multiple PT studies, trends or anomalies can be identified that would not be indicated in an individual study. Corrective or preventive action taken on trends can help to correct any biases in the test procedure and to prevent future analyses from being out of control. This procedure has been successfully used for a two-year period to track trends on multiple tests by multiple laboratories. Combined with other traditional quality assessment measures, the tracking of trends on PT studies aids in the effort to assess and improve data quality. Project managers, laboratory accreditors, laboratory managers and quality assurance professionals can use this approach, combined with other techniques, as an innovative tool to track data quality.

Introduction

Proficiency testing studies are used to evaluate laboratory performance on specific analytical tests. PT samples are defined in the National Environmental Laboratory Accreditation Conference (NELAC) Standards as samples of unknown composition to the analyst that are used to test whether analytical results can be produced within specified acceptance criteria. If test results for PT samples are within the study acceptance limits, then laboratory performance is considered acceptable and no action is generally taken. If any test result exceeds the acceptance limits, then the need for corrective action is indicated. Significant and repeated exceedances, combined with other quality control (QC) problems, may result in possible qualification or rejection of affected data or the laboratory until acceptable results can be achieved. A significant number of samples as well as laboratory revenue can be affected from the time the system went out of control until the time that the test is in control again.

In addition to using PT data to evaluate individual sample results, PT data from multiple studies can also be used to monitor trends (upward rises, downward falls, positive bias, negative bias and periodicity) and prevent outliers. While all laboratories should be concerned with outliers, this is especially important for laboratories applying for or wishing to maintain accreditation under NELAC and other regulatory or non-regulatory programs that require acceptable performance on recent PT studies (e.g., two out of three). Removal of accreditation status for repeated unacceptable PT results would not be desirable to a laboratory or their data users. By tracking performance on PT studies over time, combined with other QC measures, trends can be identified and preventive action taken if needed to improve overall data quality and prevent the occurrence of future outliers.

Background on Control Charts

A control chart is a graphical representation of the output of a process, showing plotted values of some statistic gathered from that output, a central line, and one or more control limits. A control limit is a line on a control chart that represents the maximum extent of variation in the statistic being plotted that could reasonably be expected to occur. For this paper, control charts are used to plot the results of laboratory PT studies over time. Although control charts should be maintained and interpreted in real time (such as for laboratory control samples), this paper addresses an alternative use of control charts for additional interpretation of PT study results along with other traditional quality control (QC) techniques.

Control charts are used as tools for determining an acceptable level of laboratory performance, achieving the acceptable level defined, and maintaining performance at that level. Control charts can be used to measure quality characteristics, the percent out-of-control data in a data set, and the number of out-of-control data for a given test. Depending upon the scope of performance evaluation, control limits may be based upon the capability of the process itself or defined by the applicable method, project or regulation. The frequency and evaluation of plotted information is specific to the end-user. Real-time charting, outlier tracking and historical trend analysis generally address various aspects of statistical processing and control.

There are two types of control charts: one focuses on determinations of accuracy and the other on precision. For this paper, only accuracy charts are considered and precision charts will not be discussed. A Shewhart control chart or means (X) chart is an accuracy chart that compares plotted values against an established mean in relation to statistically derived limits. The accuracy of an analyst, analysis and/or test can be evaluated by plotting determined/observed measurements of test samples (including spikes, standards, check samples and other fortified samples). An accuracy chart looks at plotted values in relation to the centerline (mean) and warning and control limits. The centerline, however, may not only reference the mean of historical determinations but also may be the actual true value of the substance analyzed or an arbitrary number. Control limits are typically set at the 95% and 99% confidence intervals or the mean $\pm$ two (1.96) sigma for the warning limits and $\pm$ three (2.58) sigma for the control limits, respectively.

Once control charting is set up for a given method, instrument or analyst, evaluation of the plots and determination of the appropriate preventive/corrective action for anomalies may commence. Analysts, laboratory supervisors and quality assurance (QA) personnel should evaluate control charts for out-of-control data and anomalies on a regular basis. Attention to the information provided by control charts may be the difference between a potential nonconformance and an out-of-control event. Emphasis should focus on proactive or preventive actions rather than curative or corrective actions.

Statistical anomalies may be described as suspicious or out-of-control occurrences. Anomalies are determined by the evaluation of plotted values in comparison to the specified warning and control limits. Both single points and points-in-series may fall into the category of being suspicious or out-of-control. These data serve as evidence to outliers, runs, trends and periodicity. Corrective and/or preventive action should be taken on each.

Outliers. There are two types of outliers: a single point that falls outside the warning limit and a single point that falls outside the control limit. A point outside the warning limit but within the control limit is suspicious in nature and, as a proactive measure, should be investigated as such. A point outside the control limit is out-of-control and must be evaluated through corrective action. Recurring or multiple outliers indicate that the initial corrective action may not have been sufficient and that additional immediate action is required. Outliers may be caused by instrument failure, inaccurate calibrations, analyst error, contamination, out-of-tolerance standards and reagents, and other problems.

Trends. An unbroken series of 4-6 or more points in an upward orientation (rise) or downward orientation (fall) is considered a trend. This pattern is suspicious in nature and, if uncorrected, could lead to a nonconformance or outlier. Trends may be caused by the degradation or concentration of standards/reagents and by changes in instrument sensitivity or performance.

Bias. A series of 6-8 or more points that line up on one side of the mean or centerline is considered a bias. This pattern is suspicious in nature, and, if uncorrected, could lead to a nonconformance. A bias may be caused by analyst error, contamination of the substance being analyzed, incorrect preparation or dilution of standards/reagents, and instrument problems.

Periodicity. A recurring pattern of change in plots in equal intervals of unspecified length or amplitude is considered periodicity. This pattern is suspicious in nature and, if uncorrected, could lead to a nonconformance. Periodicity may be caused by cyclic activities inherent in the technical procedure, matrix interferences via recurrent sampling events, and other complex occurrences.

Preventive/Corrective Actions. In the event of an out-of-control incident (outlier, beyond the control limit), the affected data should be evaluated and appropriate action taken. If the outlier is known in real time, then corrective action may be taken immediately, including re-analysis of the outlying substance in question. If re-analysis confirms the out-of-control event, then the analysis run may be suspended until the cause is determined and corrected. In the event of a potential nonconformance or knowledge of an outlier after the fact, an investigation as to the cause of the suspicious circumstances should be carried out. This may include re-calibrations, instrument servicing, preparation of new standards and reagents, re-training of personnel and other appropriate actions. All statistical anomalies should be documented via a preventive/corrective action report, marked as a nonconformance or potential nonconformance, and submitted to management and the QA department immediately.

Control Chart Procedure for Monitoring Trends

Core Laboratories' petroleum testing laboratories (including Saybolt Inc.) analyze reformulated gasoline (RFG) samples for specific tests required under the Clean Air Act – 40CFR Part 80. Accurate laboratory performance on these tests is important for ensuring that RFG used for fuel in the United States meets the standards of the Clean Air Act and that emissions are controlled. Inaccurate testing could mean that off-spec fuel is used resulting in regulatory violations and increased air pollution. Proficiency testing samples are used to monitor laboratory performance on regulated parameters,

including aromatics, benzene, distillation, olefins, oxygen (oxygenates), sulfur, and vapor pressure. U.S. EPA and American Society for Testing Materials (ASTM) methods are used for testing.

A control chart program developed by Environmental Business Strategies of Cambridge, MA (darylb@alum.mit.edu) using Microsoft Access software has been used for tracking laboratory performance on PT studies. ASTM or other interlaboratory exchange programs (round robins) are used as proficiency test samples for a variety of tests and petroleum products. For RFG analyses, the ASTM Interlaboratory Crosscheck Program is used on a monthly basis to test the required parameters. Though not required by EPA regulation, monthly crosscheck testing is an industry practice for petroleum laboratories that test RFG.

Results for each study are entered in the control chart program each month. The study mean, standard deviation and Z score (individual result – study mean / study standard deviation) from the ASTM report, as well as the reproducibility value of the test method are entered into the control charting program. ASTM flags any values with a Z score exceeding $\pm$ 2 and the control chart reflects this criteria for use in determining acceptability. Control charts and tables that display the entered and calculated data are generated each month. Data are evaluated and action taken as needed for any result(s) with a Z score exceeding $\pm$ 2. Corrective action is required for any result(s) with a Z score exceeding $\pm$ 3. In addition, data are evaluated over time for trends, biases and periodicity. If any of these anomalies are identified, preventive action is initiated to improve data quality and prevent future outliers.

Figures 1 and 2 provide examples of the control chart program output, showing tabular and graphical representations of actual GC and GC/MS data that identify an upward trend and negative bias in monthly ASTM RFG round robin data, respectively. Figures 3 and 4 provide similar examples of traditional Shewhart control charts prepared with Microsoft Excel software showing upward trend and negative bias in example PT data for environmental parameters, respectively. These charts serve as tools for defining acceptable levels of laboratory performance and for tracking trends over time. Figure 5 provides an example control chart trend analysis report used to document and act upon identified trends.

The control chart program has been used to track data from monthly RFG crosscheck samples tested by multiple testing laboratories for over a two-year period. In addition to identifying the need for corrective action on outliers, this procedure has been used to identify trends and initiate preventive action. For example, the following trends have been identified for various parameters:

- Successive points in a upward or downward direction indicating a positive or negative trend
- Successive points on one side of the mean indicating a positive or negative bias
- A recurring pattern of change in plots of equal intervals indicating periodicity
- Multiple points in succession outside the control limits (recurring outliers)
- More than one-third points outside the control limits (multiple outliers)
- Identical data for multiple laboratories indicating coincidence or possible replication of data

Identification of these trends has assisted in the initiation of preventive action, the prevention of potential outliers and improved data accuracy.

Conclusion

The use of a control chart program to track trends identified on monthly crosscheck studies has enabled the implementation of preventive action as well as corrective action to improve data quality on RFG testing required under the Clean Air Act. Commercially available software that can produce control charts can be used to track data. The use of monthly testing helps to ensure that acceptable analytical results can be produced on a regular basis. It is recommended that laboratories needing to maintain acceptable PT performance in order to obtain or retain NELAC or other accreditation consider the use of monthly PT samples, as well as the tracking of outliers and trends.

The tracking of trends on proficiency testing studies is an additional tool that laboratories and evaluators of laboratories can use to measure and help improve data quality. Laboratories can use information on trends, as well as outliers, to improve performance and prevent future outliers. Laboratory accreditors and clients can have increased confidence in laboratories that not only take corrective action on PT study outliers but also take preventive action on identified trends. This approach not only helps to prevent the occurrence of future outliers but also improves overall data quality by continually focusing on the accuracy of the test measurement. Limitations include the time needed to obtain sufficient data to monitor trends, the number of sample tests needed to prepare control charts, employee attitudes towards control charts and their usefulness, and laboratory acceptance of the need for corrective as well as preventive action.

Pre-Quality Assurance Project Plan (QAPP) Agreement (PQA)

02/29/00

National Risk Management Research Laboratory
(NRMRL)

Land Remediation and Pollution Control Division
(LRPCD)

PRE-QUALITY ASSURANCE PROJECT PLAN AGREEMENT (PQA)

Part 1. Purpose of the PQA

Prior to developing the QAPP, it is beneficial to formally document the primary objectives as well as how the data from the project will be summarized and interpreted. Part 2 of this document identifies the information that is needed to accomplish this and provides guidance on how to translate this information into hypotheses that can be evaluated using inferential statistics. In order to ensure that all project participants are aware of and agree to the primary project objectives as well as the statistical methods used to evaluate them, an agreement signature sheet is provided in Part 3. Part 4 provides two examples of completed PQAs. The first example involves a project objective where the goal is to validate a Developer's claim. The second example involves a project objective where the goal is exploratory. Part 5 provides a list of commonly used statistical terms and their definitions. For a more detailed explanation of statistical inference see the NRMRL-Ci Statistical Guidance document.

Part 2. PQA Requirements

1.0 *Briefly describe* the project.

2.0 *State* the primary objective (PO).

3.0 *State* the critical measurements necessary to realize the PO.

4.0 *State* the criteria for evaluating whether or not the PO has been achieved.

5.0 *State* the consequences of making the following errors,
•wrongly concluding the PO *has been achieved* when in fact it has *not* and
•wrongly concluding the PO *has not been achieved* when it fact it *has*.

6.0 *State* which of the two errors is the more serious and why.

7.0 *Decide* whether inferential and/or descriptive statistics will be used to summarize the results of the project.

- *Descriptive Statistics*

  If descriptive statistics are proposed, *state* what tables, plots, and/or statistics (for example, mean, median, standard error, minimum and maximum values) will be used to summarize the results. For descriptive statistics the following information is needed,

  a. a description of the experimental or sample units that will be used to generate the descriptive statistics.

- *Inferential Statistics*

  If an inferential method is proposed *state* whether the method will be a confidence interval, confidence limit, or a hypothesis test.

  For a *hypothesis test* the following information is needed,

  a. a description of the experimental or sample units that will be used to calculate the test statistic,
  b. a statement of the null and alternative hypotheses in terms of the characteristic of interest (based on Steps 1.0, 2.0, and 3.0),
  c. the Type I (") error rate[1] (based on Steps 4.0 and 5.0),
  d. a description of the proposed statistical test (for example, an equation in the case of a *t*-test for two independent samples, an ANOVA table in the case of an analysis of variance, or a statistical reference for the proposed statistical test),
  e. a statement of how the value of the test statistic will be interpreted (based on Steps 2.0 and 3.0), and
  f. a statement of how far the conclusions from the hypothesis test can be generalized[2].

  For a *confidence interval or limit* the following information is needed,

  a. a description of the experimental or sample units that will be used to calculate the confidence interval or limit,
  b. a statement of the null and alternative hypotheses in terms of the characteristic of interest (based on Steps 1.0, 2.0, and 3.0),
  c. the confidence coefficient (1 ! ") (based on Step 4.0),
  d. the equation for calculating the confidence interval or limit,
  e. a statement of how the confidence interval or limit will be interpreted (based on Steps 2.0 and 3.0), and
  f. a statement of how far the conclusions from the confidence interval or limit can be generalized[2].

8.0 Repeat the preceding steps for each primary PO.

NOTE: The Pre-QAPP Agreement is written using statistical methods derived using the classical approach to statistics because these are the methods that are the most familiar to and commonly used

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[1]For information on the relationship between sample size and error rates see the NRMRL-Ci Statistical Guidance document.

[2]For more information on how far the conclusions from an inferential method can be generalized see the NRMRL-Ci Statistical Guidance document.

by NRMRL scientists. This should not be taken as a NRMRL endorsement of any one particular approach to statistics. NRMRL advocates the choice of an appropriate statistical method based on:

- the objectives of the researcher,
- the nature of the data, and
- the available information from similar investigations.

Appropriate supporting documentation is required if non-classical approaches are proposed.

Part 3. PQA Signature Sheet

Signing below indicates agreement to the primary project objective(s) as well as the statistical method(s) used to evaluate the primary objective(s) identified in the PQA.

PQA Version (Date): _____

Name (print)	*Role - Affiliation*	*Agreement Signature*	*Date*

Part 4. Example One.
Superfund Innovative Technology Evaluation (SITE)
Demonstration and Evaluation of the KSE AIR-II Photocatalytic Reactor

1.0 *Briefly describe* the project.

This is a demonstration and evaluation of the KSE, Inc. (KSE), Adsorption-Integrated-Reaction (AIR-II) photocatalytic system. After installation at the Stamina Mills Superfund site located in North Smithfield, Rhode Island, samples will be collected and analyzed to evaluate the technology's effectiveness in treating vapors contaminated with trichloroethene (TCE). The Stamina Mills Superfund site is a former textile weaving and finishing mill. In the daily operation (early 1800's to 1975), detergents and solvents were used to clean the wool, acids and bases to color fabrics, pesticides and solvents to moth proof and plasticizers to coat fabrics. In 1969, an unknown quantity of TCE was spilled at the site and has since migrated into the soil and the bedrock aquifer beneath the site.

A dual phase extraction system was installed at the site in order to treat TCE contamination in the overburden soil and weathered portions of the bedrock. The soil vapor extraction system consists of 26 wells in the overburden to remove contaminated vapors. The multi phase extraction system consists of 31 wells installed into the saprolite/fractured bedrock to treat both contaminated vapors and groundwater. The air stream produced from this dual phase system will be treated by the KSE AIR-II. The KSE AIR-II combines two operations, adsorption and chemical reaction, to treat air streams containing dilute concentrations of volatile organic compounds.

2.0 *State the PO.*

To evaluate if the photocatalytic oxidation reactor unit can reduce TCE in the soil vapor extraction and groundwater stripper off-gases to meet the State emission standard of 0.02 lbs./hr.

3.0 *State the critical measurements necessary to realize the PO.*

TCE concentrations in the off-gas stream in lbs./hr.

4.0 *State the criteria for evaluating whether of not the PO has been achieved.*

If the TCE concentrations in the off-gas meet the State emission standard of 0.02 lbs./hr. the objective will be achieved.

5.0 *State the consequences of making the following errors,*

- *wrongly concluding the PO has been achieved when in fact it has not and*

The consequences are for example, that TCE will be released into the air at levels above the emission standards. There is the potential for adverse consequences to human and animal health, and the environment. There is also the potential for lawsuits against the Developer of the reactor unit, the State, and the Government.

- *wrongly concluding the PO has not been achieved when it fact it has.*

  The consequences are for example, that the Government will incur the additional expense of re-evaluating the technology or finding and evaluating an alternative technology. There is the potential for the Developer to incur additional research and development expenses, monetary losses from decreased sales of the reactor unit, and damage to their reputation from the failed technology demonstration.

6.0 *State which of the two errors is the more serious and why.*

The consequence of wrongly concluding the PO has been achieved when in fact it has not, is judged as the more serious error because preserving human and animal health and the environment is considered to be more important than monetary losses.

7.0 *Decide whether inferential or descriptive statistics will be used to summarize the results of the project.*

2. *Inferential Statistics*

A one-sided confidence limit will be used to evaluate the PO.

a. *a description of the experimental or sampling units that will be used to calculate the confidence limit,*

There will be 10 sampling events, one sample unit will be collected each week from the same sampling location and under the same operating conditions. Each sample collection will last approximately 60 minutes and the volume of the sample unit will be approximately 30 liters.

b. *a statement of the null and alternative hypotheses in terms of the characteristic of interest,*

H_o: $\mu \geq 0.02$ lbs./hr. versus H_a: $\mu < 0.02$ lbs./hr., where μ is the population mean concentration of TCE lbs./hr.

c. *the confidence coefficient (1 ! ")*,

A (1 ! 0.05)100% = 95% confidence interval will be used.

d. *the equation for calculating the confidence limit,*

A 95% upper confidence limit (UCL) will be calculated using the following equation,

$$UCL = \bar{x} \% \, t_{(0.05,\, n\,!\,1)} \frac{s_x}{\sqrt{n}},$$

where $\bar{x} = \left(\frac{\sum_{i=1}^{n} x_i}{n} \right)$ is the mean of the TCE measurements,

$s_x = \sqrt{\frac{\sum_{i=1}^{n} (x_i \,!\, \bar{x})^2}{(n \,!\, 1)}}$ is the standard deviation of the TCE measurements,

and n = 10 is the sample size.

e. *a statement of how the confidence limit will be interpreted, and*

If the emission standard of 0.02 lbs./hr. is greater than the UCL reject the null hypothesis and conclude that the PO has been achieved.

f. *a statement of the how far the conclusions from the confidence limit can be generalized.*

The conclusions of this project are valid for this site only.

Part 4. Example Two.
Natural Attenuation of Persistent Organics in Contaminated Sediments

1.0 *Briefly describe* the project.

This is an investigation into the mechanisms of natural attenuation of polycyclic aromatic hydrocarbons (PAHs) and natural recovery of PAH contaminated sediments. The project focuses on the creosote-contaminated sediment in the Wyckoff/Eagle Harbor Superfund Site in Bainbridge Island, Washington. The former Wyckoff wood-treatment facility became operational in the early 1900s. During its operation, large quantities of creosote were used which resulted in PAH contamination of Eagle Harbor sediments. The site has been partially capped to control PAH migration into the water column and surrounding sediments. Eagle Harbor is a shallow marine embayment of Bainbridge Island, Washington. The island is located approximately 10 miles due west of Seattle, Washington. The Wyckoff/Eagle Harbor Site was placed on the National Priorities List (NPL) in 1987 as a Superfund Site.

Four tasks will be used to investigate the natural attenuation and natural recovery processes: sediment coring, age dating, PAH weathering, and PAH fingerprinting. Sediment cores will be collected from ten locations at the Wyckoff/Eagle Harbor Site, west of the existing cap zone. If the sediment cores appear uniform, the cores will be partitioned into ten equal segments; otherwise the cores will be partitioned based on core characteristics. Assuming that a total of ten cores are collected and that each core is partitioned into ten segments, there will be approximately 100 samples for analysis.

2.0 *State the PO.*

To achieve a better understanding of the mechanisms of natural attenuation in creosote-contaminated sediments.

3.0 *State the critical measurements necessary to realize the PO.*

The following are the critical measurements for each core segment: concentrations of 50 PAH compounds; particle size determination analysis (PSD); age dating using either ^{210}Pb or ^{137}Cs; and depth and location.

4.0 *State the criteria for evaluating whether of not the PO has been achieved.*

The PO will be achieved if sufficient data are collected to investigate the mechanisms of natural attenuation of PAHs and natural recovery of PAH contaminated sediments using multivariate statistical methods.

5.0 *State the consequences of making the following errors,*

- *wrongly concluding the PO has been achieved when in fact it has not and*

  Not applicable for this exploratory PO.

- *wrongly concluding the PO has not been achieved when it fact it has.*

  Not applicable for this exploratory PO.

6.0 *State which of the two errors is the more serious and why.*

Not applicable for this exploratory PO.

7.0 *Decide whether inferential or descriptive statistics will be used to summarize the results of the project.*

A. *Descriptive Statistics*

A multivariate statistical method will be used to describe the PAH profile of the core segments over time and across depth. The PAH profile for each core segment will be constructed using the results of the chemical analysis, and standardized against a conservative chemical marker. A cluster analysis will be done on the PAH profiles. The clusters will be evaluated for meaningful partitions based on depth and/or time. Additional descriptive analyses may be performed depending on the results of the cluster analysis.

a. *a description of the experimental or sample units that will be used to evaluate the PO,*

There will be approximately 100 sample units partitioned from 10 sediment cores. Each sediment core will be approximately 10 cm in diameter and 100 cm long.

Part 5. Statistical Definitions

Alpha (α)

If the null hypothesis is in fact true, the probability of making a Type I error is denoted by the Greek symbol α. This is commonly referred to in the statistical literature as the statistical significance level. In PQA terminology, this is the probability of wrongly concluding the PO *has been achieved* when in fact it has *not*.

Alternative Hypothesis

The statement the researcher hopes is true is the alternative hypothesis (abbreviated H_a). It is also referred to in the statistical literature as the research hypothesis. In PQA terminology, this

is the statement of the *primary project objective* when the goal is to validate a claim made by the Developer concerning the performance of the technology.

To verify the research hypothesis, the investigator tries to contradict the null hypothesis. There are two types of alternative hypotheses, referred to in the statistical literature as one-tailed (one-sided or directional) and two-tailed (two-sided or nondirectional). In a directional alternative, the researcher has information to suggest the direction of the difference. For example, the mean concentration of lead at the treated site is expected to be less than the mean concentration of lead at the reference (untreated) site.

Beta ($)

If the null hypothesis is in fact false, the probability of making a Type II error is denoted by the Greek symbol $. In PQA terminology, this is the probability of wrongly concluding the PO *has not been achieved* when it fact it *has*.

Characteristic of Interest

The characteristic of interest is a critical measurement or a function of the critical measurements that is used to calculate the value of the test statistic. For example, percent contaminant reduction is a characteristic of interest that is a function of the critical measurements, before and after concentrations.

Classical Statistics

The classical approach to statistics is based on the frequency concept of probability.

Confidence Coefficient

The percentage of all possible samples of a given size yielding confidence intervals that contain the population parameter is referred to as the confidence coefficient. The confidence coefficient is represented symbolically as (1 ! ").

Confidence Limit

The two extreme points in a confidence interval are the lower and upper confidence limits or confidence bounds. The confidence limits define the range of values within which there is a specific level of confidence that the "true" population parameter will fall.

Confidence Interval

A confidence interval is a formal statistical inferential method that uses probability to draw conclusions from sample data. The confidence interval is an interval estimate for a parameter computed from the sample data. The confidence interval includes a point estimate of the population parameter (for example the sample mean) accompanied by a measure of the error associated with the point estimate.

Descriptive Statistics

An informal method for describing sample data using tables, graphical methods, and statistics. Tools for describing data include tables of the sample data and/or tables of statistics calculated from the sample data. Frequently used statistics are the mean, median, range, minimum value, maximum value, and variance of a set of sample data. Frequently used graphical methods are boxplots, dotplots, histograms, and quantile-quantile plots.

Experimental Unit

An experimental unit (EU) is the smallest unit to which a technology or treatment can be applied.

Hypothesis Test

A hypothesis test is a formal statistical inferential method that uses probability to draw conclusions from sample data with the aid of probability. Classical hypothesis testing or significance testing uses sample data to attempt to reject the null hypothesis.

Inferential Statistics

Statistical inference is a formal method for drawing conclusions from data, that takes into account the effects of chance. Probability is used to quantify how confident the researcher is that the conclusions drawn from the sample data are correct and not the result of a chance occurrence. There are two types of inferential methods, confidence intervals and hypothesis tests. Within each of these there are parametric and non-parametric methods.

Non-parametric Methods

A collection of inferential statistical methods that do not require any distributional assumptions about the characteristic of interest. Examples of non-parametric hypothesis tests include the Wilcoxon test, the Mann-Whitney test, and the Median test.

Null Hypothesis

The statement being tested is the null hypothesis (abbreviated H_o). Most often the null hypothesis is a statement of the status quo or a statement of no difference between two or more populations. In PQA terminology, this is a statement of what would occur if the claim made by the Developer concerning the performance of the technology was not achieved.

Parameter

A parameter is a quantity which is a characteristic of a population. Examples of parameters are the mean and variance of a population, represented symbolically as μ and σ^2 respectively.

Parametric Methods

A collection of inferential statistical methods that require distributional assumptions about the characteristic of interest. An example of a parametric hypothesis test that requires the characteristic of interest to follow a normal distribution is the *t*-test.

Population

The set of all experimental units of interest to the sample collector.

Power (1 ! $)

The power of a test statistic is the probability of rejecting the null hypothesis when it is in fact false. In PQA terminology, this is the probability of concluding the PO *has been achieved* when it fact it *has*.

Range

The range of a sample is the maximum minus the minimum value.

Sample

A subset of experimental units selected from a population.

Sample Unit

In some situations it is not possible to measure the entire experimental unit for the characteristic of interest. In this case, one or more sample units are selected at random from the experimental unit. The characteristic of interest is then measured for each of the sample units. For example, if a lead abatement technology is applied to a 25' x 25' plot of soil and five randomly selected portions are removed from the treated plot for measurement, the 25' x 25' plot of soil is the experimental unit and the five randomly selected portions are the sample units[3].

[3]For more information on replication and the difference between experimental and sample units see the NRMRL-Ci Statistical Guidance document.

Standard Error

The estimated standard deviation of a statistic is often called a standard error. For example, the standard error of $\bar{x}$ from a sample of size *n* and sample standard deviation of s_x is,

$$s_{\bar{x}} = s_x/\sqrt{n}.$$

Statistic

A statistic is a quantity which is computed from the sample data. Examples of statistics are the mean and variance of a sample, represented symbolically as $\bar{x}$ and s^2 respectively. Statistics are computed from sample data for two purposes: to describe the sample data; and to estimate or test hypotheses about characteristics of the population from which the sample was drawn.

Statistical Significance

Probability is used to quantify the strength of the evidence against the null hypothesis. The evidence is quantified by calculating a test statistic and determining the probability (commonly referred to as the *p*-value) of observing that particular result or one more extreme. Based on the *p*-value, the result is labeled statistically significant or not statistically significant. Traditionally, if the *p*-value is less than the Type I error (α), the result is labeled as statistically significant, and the null hypothesis is rejected. A statistically significant result is one that is unlikely to have occurred by chance.

Test Statistic

A statement of the test statistic is part of the hypothesis testing process. The test statistic is used to summarize the sample data and to make the decision whether to reject or not to reject the null hypothesis. Associated with a test statistic is the probability (commonly referred to as the *p*-value) of observing that particular value or one more extreme. Examples of parametric test statistics are the *t*-test for two independent samples and the *F*-test for more than two independent samples

Type I Error (α)

The decision *to reject* the null hypothesis, when it is in fact true is referred to as the Type I error. This type of decision error can be made only if the null hypothesis is in fact true. In PQA terminology, this is the error of wrongly concluding the PO *has been achieved* when in fact it *has not*.

Type II Error ($)

The decision *not to reject* the null hypothesis, when it is in fact false is referred to as the Type II error. This type of decision error can be made only if the null hypothesis is in fact false. In PQA terminology, this is the error of wrongly concluding the PO *has not been achieved* when in fact it *has*.

Analytical Method Checklist
for
Volatile Organic Compounds by GC/MS

03/16/00

National Risk Management Research Laboratory
(NRMRL)

Land Remediation and Pollution Control Division
(LRPCD)

TYPE OF ANALYSIS: Volatile Organic Compounds (VOCs) by GC/MS

1. INTRODUCTION:

This analytical method checklist (AMC) is intended to be a mechanism to facilitate discussions between the principal investigator (project lead) and the laboratory. Additionally, it is intended to facilitate the documentation of a project's analytical, QC, and data reporting requirements because once completed, it can be appended to a quality assurance project plan (QAPP). It is anticipated that all project matrices will be included in a single checklist.

2. APPLICABLE SAMPLES:

Describe the samples that require this analysis:

Matrix/Matrices: _____.

Sample Container Size/Type (per matrix): _____.

Sample Size (per matrix): _____ (approximate mL and/or g).

Number of Samples (per matrix): _____.

How preserved (per matrix): _____.

Other sample information *(for example, is there anything in the sample other than target analytes that could interfere with sample analysis?)*:

3. METHOD DESIGNATION:

Designate revision, date, or method number, as appropriate, in parentheses.

9	8260 ( )	**9**	Standard Methods 6210 ( )
1.	EPA500, 524.2 ( )	**9**	EPA600, 624 ( )
2.	Other ( )		

Describe or attach any deviations from the designated standard method. If uncertain regarding which method should be used, discuss this issue in advance with the laboratory. The ultimate decision of which method to use is dependent on a variety of factors including: sample matrix, sample concentration, required quantitation limits, regulatory requirements, and/or intended use of data. Do not limit the project to a particular analytical method because it happens to be a method that is more commonly used or is the only method the laboratory is capable of performing.

4. TARGET ANALYTE LIST

List or attach a list of target analytes. Designate which are critical and non-critical to project objectives and specify the required quantitation limit for each analyte. Also, list the expected concentration (or concentration range) of each analyte, if known.

Analyte lists for VOCs vary between laboratories. There is no truly "standardized list." Consult with your laboratory to be sure the lab is prepared to analyze the compounds on your list. Note: Do not set quantitation limits unnecessarily low. Increased analytical costs may result if reanalysis is required to meet quantitation limits.

5. NON-TARGET ANALYTES ("tentatively identified compounds [TICs]")

Shall non-target analytes be reported? **9** Yes **9** No

If yes, give desired number of "TICs" to report: _____, or list other criteria: _____ _____.

Discuss with the laboratory to determine if non-target analytes may be part of their "normal" calibration compounds. If so, this will provide more accurate quantitations.

6. SAMPLE HANDLING (address for each matrix)

Sample storage conditions: _____.

Maximum sample holding time: _____ hrs/days.

Methanol extract storage conditions (if employed): _____.

Methanol extract holding time (if employed): _____ days/mths.

Sample and methanol extract archiving requirement: _____ days/mths.

Other sample storage requirements:

Sample holding times vary greatly depending on matrix sample collection. Typically, holding times are 7 days for aqueous samples and 14 days for solids at 4 EC, but only 48 hours for solids in Encore samplers. Archiving is the period that the lab must hold samples under specified conditions before disposal.

7. SOIL/SLUDGE SAMPLES ONLY: MOISTURE DETERMINATION

Report as dry weight or wet weight? **9** Dry **9** Wet

If dry, separate samples must be provided for moisture determination. Describe, reference, or attach moisture determination procedure.

8. SAMPLE INTRODUCTION

Indicate which samples or matrices require which method options if all samples cannot be treated the same. Indicate by footnotes or by including information directly under the procedure chosen.

Designate revision, date, or method number, as appropriate, in parentheses.

9 Method 5030 ( ), Purge and Trap for Aqueous Samples.

_____ mL VOA vial
Purged sample volume is dependent on quantitation limit requirements.

9 Method 5035 ( ), Closed-System Purge and Trap and Extraction for Volatile Organics in Soil and Waste Samples.

9 Low concentration option (5 mL water/sodium bisulfate/VOA vial)
9 High concentration option (methanol extraction)

9 Direct injection.

9 Other _____
Describe, reference, or attach procedure.

9. QUALITY CONTROL CHECKS (QC)

The following items are included because more specific information is required than what is specified in the method. Table A contains a complete list of QC checks and needs to be revised as appropriate to meet project needs.

9.1 INTERNAL STANDARDS

9 Method recommended, see Section _____.

9 Other, specify:

9.2 SECOND-SOURCE CALIBRATION CHECK

For critical compounds, a second-source calibration check is required to validate the initial calibration. When a large number of similar compounds will be determined, a subset of representative target compounds may be used for the second-source check. Possible approaches for meeting this requirement include:

- **9** The working standard will be compared to a standard from an independent source.

  Independent Standard Description:_____

  Frequency, Acceptance Criteria: _____

- **9** A standard reference material(SRM) will be analyzed.

  SRM Description:_____
  Frequency, Acceptance Criteria: _____

- **9** The following routine QC samples are from a source independent of the calibration standard: _____ (e.g. ICV, CCC).

- **9** Other:

9.3 SURROGATE COMPOUNDS

- **9** Method recommended, see Section _____.

- **9** Other, specify:

Select surrogates that have similar chemical properties to the target analytes. For example, Table 1 of Method 8260B includes a list of possible surrogates. List surrogate acceptance criteria in Checklist Table A or reference where they can be found.

9.4 MATRIX SPIKE (MS) COMPOUNDS/LABORATORY CONTROL SAMPLES (LCSs)

Specify the MS/LCS compounds and approximate spike concentrations or how the laboratory should set spike concentrations. Also, describe when the spike is added to the sample.

The LCS referred to above is an aliquot of a clean matrix (e.g., reagent water, organic-free sand) similar to the sample matrix and of the same weight or volume. The LCS is spiked with the same analytes as the matrix spike, and at the same concentrations. Include all critical compounds in the list of MS/LCS compounds. In some cases, when a large number of similar compounds will be determined, a subset of representative target compounds may be used. Specify spike concentrations after conferring with your laboratory and considering project objectives. See Attachment 1 for LRPCD guidance on spike concentrations. VOA analyses require extra samples for use in the MS analysis unless samples were extracted with methanol. Review project QAPP to ensure sufficient sample/sample containers are provided for all QC analyses (matrix spikes, duplicates, etc.). See SW-846 Method 5000 for more guidance on matrix spikes.

10. OBTAINING DATA "WITHIN RANGE"

Definition: A compound is "within range" when the measured concentration falls between the highest and lowest calibration standards.

Background: Typically, if sample concentrations are unknown, a laboratory will run an undiluted sample. It is possible that the concentrations of one or more critical compounds will fall above the highest calibration standard and dilution will be required to bring all critical compounds within range. Alternatively, there may be one area of a site where contaminant concentration is lower compared to other areas of the site and the laboratory dilutes a sample (anticipating it will be similar to others at the site) that causes the concentrations of one or more critical compounds to fall beneath the lowest calibration standard.

If one or more critical compounds falls above the highest calibration standard, the laboratory shall take the following course of action:

If one or more critical compounds is diluted so that it falls beneath the lowest calibration standard, the laboratory shall take the following course of action:

For example, the lab may need to contact the client for further instructions or be instructed to proceed with analysis of a back-up sample. List the section of the QAPP where procedures and corrective actions can be found for handling these types of situations. This information can also be attached to this checklist.

11. REPORTING REQUIREMENTS

9 Submit data summaries to client within _____ days of

9 sample receipt **9** analysis completion **9** other, specify _____

9 Submit final data report, including QC information, to client within _____ days of

9 sample receipt **9** analysis completion **9** other, specify _____

9 Laboratory data will be archived by _____ (company name) until _____.

Laboratory reports shall include the following information:

9 Narrative--describing difficulties, deviations, and limitations to the data.
9 Cross reference table relating client and laboratory identification numbers
9 Schedule of performance, giving the dates of receipt, methanol extraction (if applicable), and analysis for all samples.
9 Target compound results. (Similar to CLP Form 1).
In addition to each result, this form will include the practical quantitation limit (PQL) for each compound, adjusted for dilution and, if applicable, percent moisture. Numerical results will be reported for those compounds for which a recognizable mass spectrum is obtained. All results < PQL shall be flagged as "estimated." For example, "2 J." For those compounds with no recognizable mass spectrum, results should be reported as "non-detect" (e.g., "ND").
9 TIC results (CLP Form I-SV-TIC or equivalent).
9 Surrogate recovery (CLP Form II or equivalent)
9 MS/MSD form (CLP Form III or equivalent)
Must include unspiked sample concentration, spiked sample concentration, spike amount, percent recovery, and all (if applicable) relative percent differences.
9 Laboratory control sample (i.e., blank spike) results
Must include spiked sample concentration, spike amount, and percent recovery.
9 Method blank summary (CLP Form IV or equivalent)
9 BFB tune form (CLP Form V or equivalent)
9 Initial Calibration Form (CLP Form VI or equivalent)
9 GC/MS continuing calibration form (CLP Form VII or equivalent)
9 Internal Standard and retention time summary (CLP Form VIII or equivalent)

The following raw data for each sample:

9 Total ion chromatograms
9 Mass spectra for identified compounds
9 Quantitation reports

- **9** Sample preparation forms, if applicable
- **9** Method detection limits from most recent determination
- **9** Chain-of-custody forms and shipping records
- **9** Other documentation, specify:

Contract Laboratory Program reporting forms are available online at:
http://www.epa.gov/superfund/programs/clp/methods.htm

Reference:

EPA. 1996. Test Methods for Evaluating Solid Waste, Volumes IA-IC: *Laboratory Manual, Physical/Chemical Methods,* SW-846, third Edition, (Revision 3). Office of Solid Waste and Emergency Response. Washington, DC.

TABLE A. Schedule of routine calibration and QC. *The following is a typical schedule based on Method 8260, but several variations are allowed by each method. Project specific requirements should be reflected in the schedule. Critical and non-critical analytes may have different acceptance criteria.*

Citation[1]	Procedure	Frequency	Acceptance Criteria	Corrective Action
7.3.1, 7.4.1	BFB tune	Prior to calibration and every 12 Hrs thereafter	Table 4, Method 8260B	Retune before analyzing samples.
7.3.5	SPCC	Every 12 Hrs., or as needed.	Minimum RF in Sec 7.3.5.4	Correct before analyzing samples.
7.3.2-7.3.4	5-point ICAL	Initially and as needed	For critical analytes, RSD of < 15%, for assumption of linearity. RRTs should be 0.8-1.2. For additional information, see Method 8000	Correct before analysis; consider non-linear calibration, repeat ICAL (consult Method 8000 for guidance).
7.4.2	ICV	Following initial calibration, prior to sample analysis.	RRF < 20% or project defined acceptance criteria	Correct before analyzing samples.
7.4.5	CCC	Every 12 Hrs.	RRF for all CCCs within 20% of ICAL.	Re-run fresh standard. Repeat ICAL. Re-run all affected samples (if possible).
8.5, 9.5	Surrogate recovery	Each sample	Project and matrix specific acceptance limits. See Table 8, Method 8260 for guidance.	Inform client ASAP; implement client specified corrective action, flag data
8.4.2, 9.5	MS/MSD or MS/DUP [2]	As specified in the QAPP or at least one/batch #20 samples	Project and matrix specific acceptance limits. For example: aqueous: 80-120% soil: 70-130%	If spike concentration for critical elements does not meet project requirements, and back-up samples are available, re-spike at appropriate concentration, and re-analyze. If spiking level is satisfactory or back-up samples are not available, notify client ASAP.
7.4.6, 7.4.7	Internal Standard	All samples	Area of IS within factor of two of area in most recent ICAL. RT within 30 seconds of time in most recent ICAL.	For all affected samples, re-analyze methanol extract or analyze back-up sample. If fails again, report both sets of data and include narrative. If persistent in other samples, solve problem before proceeding.
7.4.3	Method Blank	Each batch $\leq$ 20 samples	All critical compounds < MDL	For both critical and non-critical compounds, if sample concentration $\geq$ 10X blank, report values; For critical compounds, if contamination is within a factor of 10 of the sample concentration, find and remove source of contamination, and if possible, re-extract and re-analyze samples in affected lot; flag all affected data.

5.8, 8.4.3	LCS	Each batch ≤ 20 samples	Recovery same as for MS compounds	Find and resolve cause of poor recovery. Re-analyze affected batch (if possible). Flag data.
	MDL study	Yearly or whenever a major system change is made.	Measured MDLs << PQLs[3]	Improve MDLs before analyzing samples; inform client

[1] Citations refer to the Section in Method 8260B, unless otherwise specified.
[2] Specify whether MS/MSD or MS/Dup will be required. (MS/duplicates are recommended when sample concentrations are > practical quantitation limit).
[3] The PQL for NRMRL projects is, by default, the lowest calibration standard. Other limits may be used with justification.

KEY

ICAL = initial calibration RT = retention time RRT = relative retention time RF = Response Factor
CCC = continuing calibration check IS = internal standard SPCC = system performance check compound
LCS = Laboratory Control Sample RSD = relative standard deviation RRF = relative response factor
MS/MSD = matrix spike/matrix spike duplicate MS/DUP = Matrix Spike/Sample Duplicate
ICV = initial calibration verification BFB = 4-Bromoflurobenzene MDL = Method Detection Limit
PQL = Practical Quantitation Limit

ATTACHMENT 1
LRPCD Spiking Level Recommendations

Matrix Spike (MS)

A known concentration of target analyte is spiked into one of two aliquots of an actual sample prior to preparation (if applicable) or analysis. Spiking levels should be determined as follows:

(1) For projects where there exists a regulatory level of concern, and sample target analyte concentrations are expected to be near or below that regulatory level of concern, the concentration of the MS addition should be at the regulatory level of concern. *Note: this assumes that the regulatory level of concern is at least 5-10 times the method detection limit.*

(2) For projects where there is no regulatory level of concern, and the sample target analyte concentrations are expected to be near or below the method detection limit, the concentration of the MS addition should be at least ten times the method detection limit.

(3) For projects where sample target analyte concentrations are expected to be well above the regulatory level of concern or the method detection limit, the concentration of the MS addition should be at least one to five times the background level of the target analyte.

(4) For projects where sample target analyte concentrations are so high that spiking is not feasible, choose another method (e.g., LCS, SRM) to evaluate accuracy. In addition, consider the potential value of spiking sample dilutions.

Approaches to Systematic Planning for Environmental Operations

Duane Geuder,[a] U.S. EPA, Office of Emergency & Remedial Response; Marguerite E. Jones,[b] DynCorp I&ET, Inc.; Leslie J. Braun,[c] DynCorp I&ET, Inc.; Paul E. Mills,[c] DynCorp I&ET, Inc.; and Conrad O. Kleveno,[b] DynCorp I&ET, Inc.

Use of a systematic planning approach to develop acceptance or performance criteria is required under the revised EPA Quality Order (EPA Order 5360.1 CHG 1) for all work covered by the scope of that Order. The EPA Quality Manual for Environmental Programs, EPA Order 5360, continues the discussion of systematic planning, stating it should be based on the scientific method. The planning process should be based on a common sense, graded approach to ensure that the level of detail in planning and the performance criteria are commensurate with the importance and intended use of the work and the available resources. There are several specific elements of a systematic planning approach documented in the Orders.

The intent of a systematic planning process is to ensure that all organizations and/or parties who contribute to the quality of the environmental program or use the results are identified and that they participate in this process. The planning process should also provide for direct communication between the customer and the supplier to ensure that there is a clear understanding by all participants of the needs and expectations of the customer and the product or results to be provided by the supplier. EPA has developed a systematic planning process called the Data Quality Objectives (DQO) Process (EPA QA/G-4, currently undergoing revision). While not mandatory, the EPA Quality Staff recommends this process as the planning approach for many EPA data collection activities.

There are many barriers to the universal use of the DQO Process across EPA, ranging from psychological through the mathematical to the financial. Other Federal agencies, associations, and academia have developed various systematic planning and decision support processes, many of them directly related to environmental operations, that may be useful to EPA decision makers when planning and implementing environmental operations. The U.S. Army Corps of Engineers' Technical Project Planning Process, the Bureau of Reclamation's Decision Process, and others may serve as models adaptable to various environmental operations under EPA's

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[a]Geuder: U.S. Environmental Protection Agency (5202G), Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460

[b]Jones & Kleveno: DynCorp I&ET, Inc., 6101 Stevenson Avenue, Alexandria, VA 22304

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domain. This paper summarizes and contrasts the various approaches identified.

Use of a systematic planning approach to develop acceptance or performance criteria is required under the revised EPA Quality Order (EPA Order 5360.1 CHG 1) for all work covered by the scope of that Order. The *EPA Quality Manual for Environmental Programs*, EPA Order 5360, continues the discussion of systematic planning, stating it should be based on the scientific method. The concept of the Scientific Method is to observe, create a hypothesis based on what was observed, and use the hypothesis to make a prediction and test the hypothesis. One should continue to test until there are no discrepancies between the hypothesis and the prediction. EPA Order 5360 lists eight elements of systematic planning that are based on the scientific concept. The eight elements are:

- Identification and involvement of the project manager, sponsoring organization and responsible official, project official, project personnel, stakeholders, scientific experts, etc. (e g., all customers and suppliers);

- Description of the project goal, objectives, and questions and issues to be addressed;

- Identification of the project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements);

- Identification of the type of data needed and how the data will be used to support the project's objectives;

- Determination of the quantity of data needed and specification of performance criteria for measuring quality;

- Determination of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection;

- Specification of needed QA/QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);

- Description of how acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the quality performance criteria.

The intent of a systematic planning process is to ensure that all organizations and/or parties who contribute to the quality of the environmental program or use the results are identified and that they participate in this process. The planning process should also provide for direct communication between the customer and the supplier to ensure that there is a clear understanding by all participants of the

needs and expectations of the customer and the product or results to be provided by the supplier. Systematic planning is required when implementing a performance-based measurement system (PBMS). EPA has developed a systematic planning process called the Data Quality Objectives (DQO) Process (EPA QA/G-4, currently undergoing revision). While not mandatory, the EPA Quality Staff recommends this process as the planning approach for many EPA data collection activities.

The Concept of Data Quality Objectives

DQOs are defined in EPA QA/G-4 as "[q]ualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions." DQOs should be part of the sampling and analysis plan; they should be both comprehensive and measurable and specify the amount of uncertainty acceptable.

The understanding of DQOs has evolved since 1980 when EPA published its *Interim Guidelines and Specification for Preparing Quality Assurance Project Plans*, QAMS-005/80. At that time, quality objectives were presented in terms of Precision, Accuracy, Completeness, Representativeness and Comparability (the "PARCC parameters"). In EPA Acquisition Regulations concerning *Quality Assurance Project Plans* written in 1984, DQOs were still defined in the terms of PARCC parameters (and the implication was that contractors, not the EPA decision-makers, were to determine the DQOs).

Other publications refer to DQOs, but the examples of DQO statements in those publications vary; none appears comprehensive. For example, the Data Quality Objectives Decision Error Feasibility Trials (DEFT) software was developed by QAMS in 1994 to reduce the need for iteration in the last two steps in EPA's current DQO process. DEFT uses the outputs from earlier DQO process steps; in Figure 3 of QA/G-4D and the text following, DEFT defines DQOs in terms of Action Level, Standard Deviation, Decision Error Limits, the Gray Region, and the Null Hypothesis.

The Quality Assurance Sampling Plan for Environmental Response (QASPER) is software that combines user-selected technical text and user-provided, site-specific information into a sampling plan. QASPER was created to facilitate the timely assembly of a comprehensive sampling plan for environmental response actions. QASPER defines DQOs in terms of confidence levels or acceptable limits for making a decision error; QASPER also assumes that only one confidence level is applicable to a project or sampling event.

DQO-PRO is an electronic calculation program that can be used to help plan the minimum number of samples that should be collected. DQO-PRO, like DEFT, was designed to ease iteration between the last two steps in the current DQO process. Waste Policy Institute's Dr. Larry Keith, a developer of DQO-PRO, prepared a series of tutorials on the use of the product. In a background on DQOs, Dr. Keith stated that an example of a qualitative DQO statement would be descriptions of actions to be taken if objectives are not met; for example, what to do if quality control samples are contaminated. According to Dr. Keith, quantitative DQO statements would be descriptions of actions to be taken if

Measurement Quality Objectives (MQOs) are not met. For example, specified percent recovery of analytes from spikes; standard deviation as precision from replicate samples; or completeness as a percentage of valid measurements of total. Dr. Keith makes it clear that MQOs based on PARCC parameters are only a subset of overall project DQOs.

The final version of EPA QA/G-4HW, published in January 2000, walks the reader through a hazardous waste DQO case study. It does a good job detailing the steps in the process but falls short of clearly specifying the resulting DQOs. It merely states, in Appendix C, "[t]he team ordered the test kits, finalized the DQO outputs, and documented key discussions and assumptions. This information was a critical input for the next activity leading to the Phase 1 data collection, the development of the QA Project Plan." It is not clear to the reader if the "DQO outputs" referred to are synonymous with "DQOs," and if so, what the specific DQOs for this case study were. It is also unclear precisely how the DQOs were documented in a QA project plan.

EPA has developed alternate terminology for DQOs, "acceptance or performance criteria" in EPA Order 5360.1 CHG 1. EPA Order 5360 uses the terms "quality objectives and criteria for measurement data" and "measurement performance criteria." No examples were provided in either document.

The Evolution of EPA's DQO Process

EPA's Data Quality Objectives Process has evolved since its inception in circa 1986. The DQO process initially consisted of three stages:

- Stage One - Define the question or decision;
- Stage Two - Clarify and precisely state what information is needed;
- Stage Three - Design the data collection program.

The three stages, each with multiple steps, have been refined over time and have become EPA's current DQO process that is a based on the following seven steps:

1. State the Problem
2. Identify the Decision
3. Identify the inputs to the Decision
4. Define the Study Boundaries
5. Develop a Decision Rule
6. Specify Tolerable Limits on Decision Errors
7. Optimize the Design for Obtaining Data

Resistance to Systematic Planning

Even though the DQO process has been refined, there is still much resistance to its use in systematic planning. There are many barriers to the universal use of the DQO process across EPA, ranging from psychological through the mathematical to the financial. It is regarded as requiring too many stakeholders, making the process too complex. In time-critical projects, the DQO process is viewed

as too time-consuming, especially in cases where only one possible outcome is perceived. Managers see its use as detracting from their use of "professional judgment" in data collection and evaluation. Use of the DQO process can involve the need for the assistance of a statistician, which may not be available or affordable on the project. There is also the chicken-and-egg syndrome, in which quantitative information about the project is needed to develop quantitative statements on tolerance limits for the quality of the data to be collected; however, one needs to collect the data to have the quantitative information to develop these statements for subsequent data collection.

Step 6 of the DQO process requires one to specify tolerance limits on the risk of making decision errors. In regulatory or enforcement scenarios, many decision-makers are uncomfortable expressing the reality that a decision error might exist, much less quantify that risk. For others, the statistical term "error" is misinterpreted as professional error, an insult.

Finally, although represented as a graded approach to systematic planning, the guidance on the DQO process does not clearly demonstrate its applicability to small projects or to non-probabilistic sampling approaches.

Other Systematic Planning Processes

Despite these barriers, other Federal agencies, associations, and academia have developed various systematic planning and decision support processes, many of them directly related to environmental operations, that may be useful to EPA decision makers when planning and implementing environmental operations. The U.S. Army Corps of Engineers Technical Project Planning Process, the Bureau of Reclamation's Decision Process, and others may serve as models adaptable to various environmental operations under EPA's domain. These approaches are summarized below.

U.S. Army Corps of Engineers' Technical Project Planning (TPP) Process – The USACE's TPP process was designed to ensure conformance to ANSI/ASQC E4 and simplify EPA's planning requirements. The TPP process consolidates the DQO process into four phases:

- Phase I: Identify Current Project
- Phase II: Determine Data Needs
- Phase III: Develop Data Collection Options
- Phase IV: Finalize Data Collection Program

Compared to the DQO process, the TPP process activities, guidance, and tools provide more explicit guidance in designing a data collection program for a site. TPP is used when planning any activities at a site (i.e., site investigation; design; construction, operation and maintenance; or long-term monitoring). Contact Larry Becker, (202) 761-8882.

U.S. Department of Energy Streamlined Approach for Environmental Restoration (SAFER) – DOE developed SAFER as a methodology tailored to the challenges of conducting environmental restoration efforts under conditions of significant uncertainty. SAFER was developed primarily by integrating the DQO Process with the Observational Approach (OA), or "learn-as-you-go." SAFER

does not use the "seven step" format explicitly, but implicitly incorporates the process in describing the steps in Remedial Investigation/Feasibility Study (RI/FS) planning through to the Remedial Design/Remedial Action (RD/RA) phase of environmental restoration. SAFER was developed for use in streamlining the iterative process between determining the type and extent of contamination at a site and identifying and evaluating cleanup alternatives. It is a corollary to EPA's Superfund Accelerated Cleanup Model (SACM). Contact Analytical Services Division, (301) 427-1677.

Bureau of Reclamation's Decision Process – The U.S. Bureau of Reclamation's Decision Process is broader in scope and designed to be used for a variety of operations, environmental or otherwise. It integrates the spirit of the DQO process (using eight steps for planning) and continues the process through implementation and follow-up. Case studies available include a National Environmental Policy Act compliance study and a study on environmental indicators, demonstrating its flexibility. Contact Thayne Coulter, (303) 445-2706.

Each of these three processes, as well as EPA's DQO process, meets the eight elements of systematic planning described in Order 5360 and included above.

The Choices

The use of systematic planning is required; decision-makers have no option to avoid the planning process. They do have a choice of method, however.

If stakeholders are perceived as making the process too complex, managers should recognize that some champions of the SAFER process, for example, tout its utility in obtaining regulators' approvals of plans much more quickly, because the regulators were involved from the start.

If the DQO process is viewed as too time-consuming on time-critical projects, managers might obtain agreement from potential stakeholders on what minimum, or typical, or routine, or presumptive quality performance criteria might be under defined circumstances. Then the managers could use a "learn-as-you-go" method, keeping the stakeholders involved as the project unfolds, to refine the quality performance criteria and obtain data to meet them.

If managers see the use of the DQO process as detracting from their use of "professional judgment" in data collection and evaluation, managers should realize that a project typically has numerous technical aspects to it, and stating specific quality performance criteria to address all the technical aspects will demonstrate their professionalism. Decisions will not be perceived as arbitrary or capricious.

If statistical support is not needed or not affordable, managers should remember that EPA Order 5360 does not require the use of statistics. There is only a requirement that the stakeholders identify the type of data needed and how the data will be used to support the project's objectives. According to its definition, DQOs can be qualitative as well as quantitative. (The Agency still requires data of known quality, however.)

If a graded approach to systematic planning is required, the TPP process provides clear guidance on its use for specific types of projects. The Bureau of Reclamation's Decision Process description provides an array of quality management tools, including quasi-quantitative ones (e.g., ranking techniques, decision trees, frequency diagrams), that may be useful on some projects.

Conclusion

EPA requires the use of systematic planning, no matter which approach is used. Although systematic planning is required, a "public relations" campaign may be needed to provide potential uses with a carrot instead of a stick. As highlighted in this paper, there are several approaches that could serve as a model when designing the approach that best fits an organization and the flexibility that may be needed based on specific work processes. Ideally, a series of case studies of projects large and small should be assembled. The authors are currently identifying case studies in which each of these methods were successfully used in environmental data operations to understand the benefits as well as the lessons learned in each use.

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How Quality Assurance Shapes the Multi-Agency Radiation Survey and Site Investigation Manual

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The Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) is a technical document designed to assist in the demonstration of compliance with cleanup standards for radioactively contaminated sites. The MARSSIM is a consensus document developed by technical staff from Departments of Defense, Air Force, Army, Navy (DOD) and Energy (DOE), the Environmental Protection Agency (EPA), and the Nuclear Regulatory Commission (NRC). The focus of MARSSIM is on data quality; that is, to provide guidance for planning, conducting, evaluating and documenting environmental radiological surveys in such a way that the data can be used to make the decisions that are needed. The MARSSIM presents a decision framework for designing the questions to be asked, and using these questions as drivers for the data to be gathered. Survey data are obtained through a phased process that involves developing detailed plans using the DQO process, conducting the survey, and using the Data Quality Assessment (DQA) process to evaluate the data. The DQA determines if the survey objectives that were established in the planning stage were met. During the final decision, the data are used to determine if the site or portions of the site meet the release criteria. The DQO process described in the MARSSIM ensures that there is flexibility to address the large diversity in sites and agency requirements to which MARSSIM is applicable. The MARSSIM decision process applies to the release of surface soils (to 6 inches) and building surfaces on a site. Areas outside the scope of MARSSIM include the evaluation of subsurface (deeper than 6 inches) and groundwater contamination. The MARSSIM can be used by a wide variety of organizations and regulatory programs to demonstrate that a site meets the release criteria without having to "reinvent the wheel" and justify their methods and derivations. As more radiation professionals are being trained and becoming familiar with the MARSSIM, its methods are being applied by States, Tribes, federal agencies, and the private sector.

There are thousands of sites throughout the United States where radioactive materials have been processed and stored. These sites range in size from large tracts of land devoted to federal weapons-production to small nuclear medicine departments of hospitals to abandoned manufacturing facilities where the extent of the contamination is unknown. Local officials and owners of many of these sites need methods to determine if these sites are above allowable limits after decontamination so that they can be released for public use.

What MARSSIM Is

The MARSSIM document describes a series of steps for deciding on the types and numbers of measurements that should be conducted to answer the questions that are posed by managers of radiologically contaminated sites. This includes a structure for how to make decisions about whether lands (soil to a depth of 6 inches) and buildings meet a release criterion for radiological contamination. The process described in the MARSSIM begins after the release criterion, in measurable units such as pCi/g or Bq/m^2, has been set. In general, these release criteria are based on risk and must be translated into measurable units (derived concentration guideline levels, or DCGLs) using modeling and assumptions. Obtaining and interpreting the data needed to decide whether these DCGLs have been met is the focus of MARSSIM.

The document describes the steps that can be used to evaluate how many measurements need to be made, of what type, and their locations. These factors are dependent on the degree of confidence associated with the decision as well as factors about the site, such as the variability in and types of contamination that are known to exist. Extensive information on the types of measurement techniques and where they are appropriate is included in the MARSSIM.

What MARSSIM Is Not

The MARSSIM scope does not include guidance for the release of non-real property such as equipment and personal items or small objects and materials that leave the site. Also excluded are soils at a depth greater than 6 inches and contaminated water and chemical hazards. The MARSSIM also does not provide guidance on judgmental measurements such as those intended to locate contamination in pipes, drains, ducts, fixtures and inaccessible areas. It is important to recognize also that MARSSIM does not provide mechanisms for translating dose or risk limits into measurable units; the MARSSIM process is separate from the determination of the DCGLs.

Terminology

A *survey unit* is a physical area, consisting of structures and/or land areas, of specified size and shape for which a separate decision will be made as to whether or not that area exceeds the release criterion. The size and shape of the survey unit are based on factors such as the potential for contamination, the expected distribution and variability of the contamination, and any physical boundaries (e.g., buildings, fences, soil type, surface water body, etc.) at the site. Areas are classified in accordance with their potential for contamination and small areas of elevated activity.

Direct measurements are measurement of radioactivity obtained by placing the detector near the surface or media for sufficient time to measure the level at that location. An indication of the resulting radioactivity level is read out directly.

Scanning measurements are performed by moving a detection device over a surface at a specified speed and distance above the surface to detect radiation.

Samples are gathered for subsequent laboratory analysis as specimens of the material in the survey unit or reference area.

Elevated Measurement Comparison (EMC) tests are performed on the data in conjunction with the Wilcoxon rank sum test or Sign test to determine if there are any measurements that exceed a specified value.

Reference areas (background areas) are defined as areas that have similar physical, chemical, radiological, and biological characteristics as the site area being remediated, but which has not been contaminated by site activities. The distribution and concentration of background radiation in the reference area should be the same as that which would be expected on the site if that site had never been contaminated. More than one *reference area* may be necessary for valid comparisons if a site exhibits considerable physical, chemical, radiological, or biological variability.

The *Wilcoxon Rank Sum (WRS) test* is a nonparametric statistical test used to determine compliance with the release criterion when the radionuclide of concern is present in background.

The *Sign test* is a nonparametric statistical test used to demonstrate compliance with the release criterion when the radionuclide of interest is not present in background and the distribution of data is not symmetric.

The *Derived Concentration Guideline Level (DCGL)* is a radionuclide specific activity concentration (e.g., pCi/g or Bq/m^2) that corresponds to the release criterion. The DCGL is derived (separate from the MARSSIM process) using various exposure pathway scenarios and dose/risk models.

Small Areas of Elevated Activity are maximum point estimates of contamination or hot spots. (The MARSSIM does not use the term "hot spot" because the term often has different meanings based on operational or local programmatic concerns.)

Alpha (α) is the specified maximum probability of a type I error. In other words, the maximum probability of rejecting the null hypothesis when it is true. Alpha is also referred to as the size ofthe test. Alpha reflects the amount of evidence the decision maker would like to see before abandoning the null hypothesis.

Beta (β) is the probability of a type II error, i.e., the probability of accepting the null hypothesis when it is false. The complement of beta ($1-\beta$) is referred to as the power of the test.

The MARSSIM Process

The data quality objectives (DQO) Process, which is integrated into the recommendations in the MARSSIM, presents a method for building common sense and the scientific method into designing and conducting surveys. To make the best use of resources, the MARSSIM places greater survey efforts

on areas that have, the highest potential for residual contamination, using the graded approach to planning and making the measurements. The MARSSIM begins with an evaluation of the existing information on the site so that the measurements can be planned in accordance with this information.

The minimum information (outputs) required from the DQO Process in order to proceed with the methods described in the MARSSIM are:

- the boundaries of the survey units and the classification of the units;
- the null hypothesis (H_0). The MARSSIM uses "The residual radioactivity in the survey unit exceeds the release criterion";
- specification of a gray region where the consequences of decision errors are relatively minor;
- Type I and Type II decision errors and probability limits for the occurrence of these errors;
- the estimated standard deviation of the measurements in each survey unit; and
- the detection limit for all measurement techniques (scanning, direct measurement, and sample analysis).

This information is then used to determine the number of samples or measurements and their locations.

As survey units are identified, reference coordinate systems are established, and background reference areas are selected. The survey plans for measuring the uniform contamination using sampling and direct measurements are initially developed separately from plans to collect data on small areas of elevated activity (hot spots) which are based on scanning. For estimating uniform contamination, plans provide the number of samples to be taken, their locations, and based on the minimum detectable concentration (MDC), the detection methods to be utilized. For small areas of elevated activity, plans include the selection of scanning devices based on the scan MDC and the determination of the scanning coverage. The independently developed survey plans for measuring the uniform contamination and for finding small areas of elevated activity are then integrated into one plan called the Integrated Survey Plan. The overall plan must compensate for any deficiency in any one part. For instance, if the scan sensitivity is insufficient to meet the criteria for making decisions on small areas of elevated activity, an increased number of samples (higher sample density) can be used to compensate for the scanning deficiency.

MARSSIM Sampling

The intent of the statistical approach is to satisfactorily represent the distribution of residual radioactivity in the survey unit with the least number of samples. Non-parametric statistical tests are used to minimize the dependence on normality since many of these sampling distributions are skewed by small areas of localized radioactivity that can result from remediation activities.

Sampling and how to interpret sampling data are key to MARSSIM. If the scanning sensitivity is not adequate to show that the release criteria are met then sampling is required. Sampling and direct measurements cannot fully replace a 100% scan in terms of spatial coverage and therefore the location and number of the samples must provide enough information about the overall distribution of residual radioactivity to make a decision regarding the survey unit status. Rigorous statistical methods must

therefore be applied to estimate the distribution of the residual radioactivity by analyzing a representative sample distribution.

The number of samples needed to properly assess the true distribution of residual radioactivity for a given survey unit is closely associated with the quantity Δ/σ. Δ is the width of the gray region, which is the range of values of the measurement where the consequences of making a decision error are relatively minor. The upper bound of the gray region in MARSSIM is set equal to the DCGL, and the lower bound is decided upon by the site managers. σ is the measured or estimated standard deviation in the residual radioactivity.

The ratio Δ/σ is an indication of how much effort is needed or how precise the real distribution of residual radioactivity must be known to demonstrate that the survey unit can be released. When σ is small compared to Δ, the ratio is large and the mean of the distribution can easily be determined to be above or below the DCGL. It is therefore critical to define survey units in which the contamination is relatively uniform. Only few samples are needed to demonstrate compliance with the DCGL (i.e. Δ/σ greater than 3). When σ is large compared to Δ, the ratio is small and many more samples are needed to know the distribution more precisely (i.e., Δ/σ less than 1). MARSSIM works well when Δ/σ is in a range between 1 and 3. This is where the statistical rigor is most effective in resolving the data. In this region a survey plan can be developed and the distribution known well enough to provide a decision regarding the survey unit status. Δ/σ can be adjusted by selecting different values for α, β, and the lower bound of the gray region in the survey plan.

Quality control measurements are used to monitor the performance of measurement systems during implementation of the survey plan. The goal is to identify potential problems early and ensure that the survey design objectives are met.

In the assessment phase, the data are inspected and validated. The data are checked to determine if the expected parameters and assumptions, developed during the planning stage using the DQO process, are supported by the actual data. A preliminary data review explores the structure of the data and identifies patterns, relationships, or potential anomalies. This review should include calculating basic statistical quantities *(i.*e., mean, standard deviation, median) and graphically presenting the data using a histogram and a posting plot.

The final step in interpreting the data is the decision on the survey unit. The statistical test is conducted to determine if the average value of the data distribution meets the DCGLs. Tables 1 and 2 summarize the statistical tests recommended in MARSSIM. The Sign test is performed when the contaminant is not present in background (as measured in the reference area), and the Wilcoxon Rank Sum (WRS) test is performed when the contaminant is present in background. The Elevated Measurement Comparison test is conducted to demonstrate that localized contamination does not exceed the threshold for small areas of elevated activity identification. The result of the EMC is not conclusive as to whether the survey unit meets or exceeds the release criterion, but is a flag or trigger for further investigation. Both the WRS and Sign test and the elevated measurement comparison test must be passed to demonstrate that the DCGLs are met.

The result of the Sign test or the WRS test is the decision to reject or not to reject the null hypothesis that the survey unit is contaminated above the DCGL. Provided that the results of any further investigations triggered by the EMC test have been resolved, a rejection of the null hypothesis leads to the decision that the survey unit meets the release criterion. If necessary, the amount of residual radioactivity in the survey unit can be estimated so that dose or risk calculations can be made. In most cases, the average concentration is the best estimate for the amount of residual radioactivity.

Table 1: Recommended Tests When the Radionuclide is Not in Background and Radionuclide-Specific Measurements Made:

Survey Result	**Conclusion**
All measurements less than the DCGL	The survey unit meets the release criterion
The average is greater than the DCGL	The survey unit does not meet the release criterion
Any measurement is greater than the DCGL and the average is less than the DCGL	Conduct the Sign test and the elevated measurement comparison test

Table 2: Recommended Tests When the Radionuclide is Present in Background or Radionuclide Non-Specific (Gross) Measurements Made:

Survey Result	**Conclusion**
The difference between the maximum survey unit measurement and the minimum reference area measurements is less than the DCGL	The survey unit meets the release criterion
The difference of the survey unit average and the reference area average is greater than the DCGL	The survey unit does not meet the release criterion
The difference between any survey unit measurement and any reference area measurement is greater than the DCGL and the difference of the survey unit average and the reference area average is less than the DCGL	Conduct the WRS test and the elevated measurement comparison test

Quality of Decision

The power curve provides information on the probability that a survey unit will pass if the true median of the distribution is below the DCGL. As the number of samples is increased, the true distribution of residual radioactivity will be better known, and therefore the probability that the survey unit will pass will be higher for a given true value below the DCGL. Figure 1 illustrates this by displaying the different

power curves for the different data sets containing the different number of samples taken. The power curves representing the larger data sets have higher probabilities of passing as the true median value approaches the DCGL. Consider the case where an infinite number of samples are taken at every point within the survey unit. The distribution of residual radioactivity will be known exactly and the mean of the distribution can be determined to be below the DCGL with a 100% probability for any true mean value below the DCGL. However, real distributions are never known exactly, and there is some potential risk to failing the statistical tests for a given finite sample set.

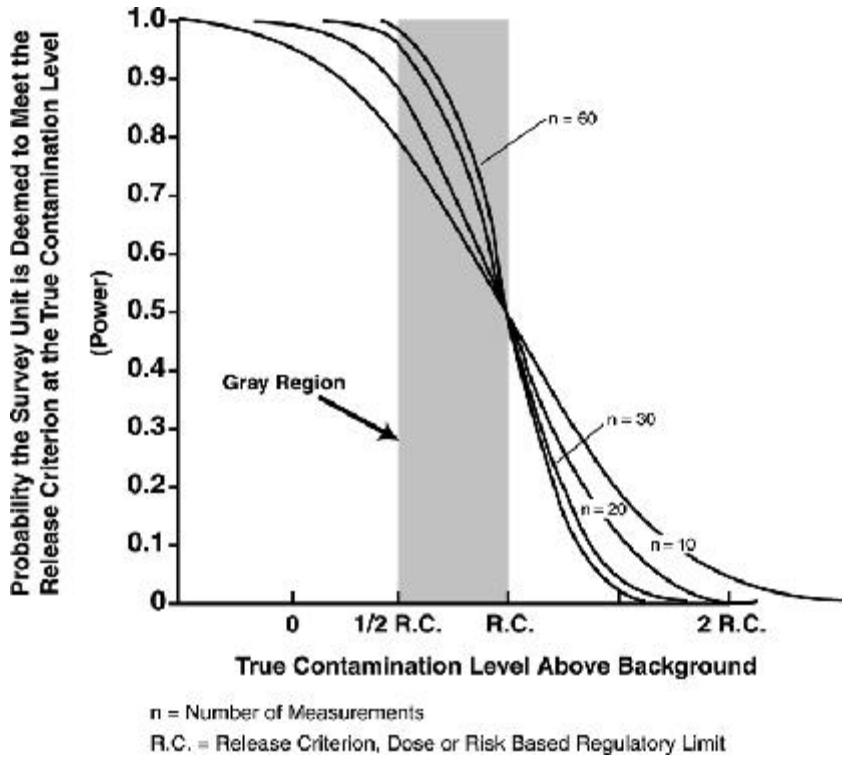

Figure 1 – Power Curves for Different Data Sets with Different Numbers of Data Points

Conclusion

The MARSSIM process has been used at sites throughout the U.S. Nearly five hundred people from state, local, and federal agencies and the private sector have taken classes in the implementation of the methods described in the MARSSIM. Its growing use and adaptation in many sites present the possibility of adding efficiency and consistency to the important field decommissioning radioactively contaminated sites.

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CLP Data Assessment Tool (DAT) - Innovations in Quality Assessment Tools and Techniques

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Since 1980, USEPA's OERR Analytical Operations/Data Quality Center's (AOC) Contract Laboratory Program (CLP) has been providing laboratory analytical data of known and documented quality on a high-volume, cost effective basis for the Superfund program. CLP data is used to demonstrate the nature and extent of contamination at hazardous waste sites, assess priorities for response based on risks to human health and the environment, establish appropriate cleanup actions, and determine when remedial actions are complete. The CLP has been evolving over the last several years to become more flexible and to focus on customers' changing needs. The CLP's new electronic Data Assessment Tool (DAT) expedites the evaluation of site data, which results in quicker site responses. DAT significantly reduces data assessment turnaround time from 21-30 days (or more) to 24-48 hours and saves data review dollars. Since the implementation of this service, more than $2.7 million has been saved under the CLP's organic and inorganic programs.

Introduction and Background

USEPA's Contract Laboratory Program (CLP) is a national network of USEPA personnel, commercial laboratories, and support contractors whose fundamental mission is to provide data of known and documented quality. The CLP supports USEPA's Superfund effort originally under the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and under the 1986 Superfund Amendments and Reauthorization Act (SARA).

The CLP provides data through its routine chemical analytical services. Its supporting services ensure that known quality data is provided to CLP users. Because of its supportive infrastructure, the CLP is able to provide all services in a cost effective and efficient manner. Currently the CLP offers three Routine Analytical Services (RAS): multi-media, multi-concentration organic analytical services; multi-media, multi-concentration inorganic analytical services; and low-concentration organic analytical services. CLP services allow users the option to combine analytical parameters, data turnaround times, and detection limits. The CLP is also developing services for dioxin and PCB congener/homolog analyses.

All analytical services are performed by USEPA contract laboratories that meet stringent requirements and standards (e.g. On-site audits, PE samples, etc.) in order to be a part of the CLP. Each sample processed through the CLP is properly documented to ensure timely and accurate analysis for requested parameters. This process also ensures that CLP data can be reliably used in potential enforcement actions and cost recovery.

CLP data is used to:

1. Demonstrate the nature and extent of contamination at Superfund sites;
2. Determine appropriate cleanup, emergency response, and remedial actions; and
3. Support enforcement/litigation activities.

CLP data may be used in all stages of hazardous waste site investigations, including site inspections, Hazardous Ranking System scoring, remedial investigation/feasibility studies, and remedial design.

The CLP has implemented a number of supporting services to ensure that known quality data is provided to its CLP customers. The Sample Management Office (SMO), operated by DynCorp under USEPA's Contract Laboratory Analytical Support Services (CLASS), was established to provide centralized operational support to help AOC meet program challenges. The Contract provides services necessary to schedule, track, invoice and assess laboratory data to help AOC to accomplish its mission of guaranteeing that CLP analytical services are effectively monitored and utilized. In addition, SMO acts as the repository for both hard copy and electronic data. QATS, the Quality Assurance Technical Support Contractor provides performance evaluation samples, assists with onsite audits, conducts data tape audits, and evaluates new methods.

What is the role of data in the CLP, how is it used?

Laboratory data produced by CLP laboratories are submitted to USEPA Regions and DynCorp concurrently. This data is reviewed for technical and contractual compliance by both USEPA Regions and SMO. The data collected through Regional and SMO reviews are used for many purposes, including, but not limited to, enforcement, performance evaluation, method evaluation, modeling/mapping, remediation, site investigation, and cost recovery.

USEPA's Regional data review process is most commonly referred to as data validation. Data validation on large environmental investigation projects has traditionally been one of the slowest parts of the entire analytical process. Traditionally, laboratory data was reviewed manually, spreadsheets of analytical results and qualifying flags were constructed, and spreadsheets of data were transferred into reporting tables for project clients and decision-makers. This process often introduced errors due to these multiple transcriptions and the re-keying of data and associated qualifiers.

Lengthy data assessment and validation can result in delayed decisions, which can mean delayed cleanup and greater environmental impact, requiring greater remediation efforts. If field equipment and crews have to remain on-site until the sample results have been validated, costs continue to mount. If they leave and have to go back to resample, additional mobilization costs are incurred. DAT provides data more quickly than was traditionally possible to data validators, enabling data users to make decisions sooner about whether or not to leave a site or continuing to collect more samples.

DAT Case Study/Pilot

In February 1998, USEPA Region II's Superfund Division Director declared the Federal Creosote site in New Jersey to be a high priory site. Approximately 133 occupied residences were located on or near the site. In order to quickly assess the level and extent of contamination, environmental damage, and possible risks to human health, Region II initiated a massive sampling effort. Due to the high public visibility of the site, the type of analyses, and the large number of samples involved, Region II requested AOC's support.

Due to high volume of samples (approximately 3,000), AOC recognized the need for a process tool that would allow for rapid data transfer and storage of analytical data. Regional data validation has typically required manual data entry or re-keying of data that has already been reviewed using Contract Compliance Screening (CCS) and Computer-Aided Data Review and Evaluation (CADRE). With no way to transfer the results of this evaluation into other formats or programs, these activities required a duplication of time and effort.

The Federal Creosote project required unusually fast data turnaround and required atypical data transfer and storage. AOC worked with SMO to develop and implement a new analytical data assessment tool that could be used by the Region during the data validation process and provide a way to rapidly transfer the results of this data validation to the data user. During the Federal Creosote project, DAT made it possible to transmit qualified electronic data to the Region within eight (8) hours of the Data Receipt Date. Performance evaluation samples were also shipped to the CLP laboratories for every other Sample Delivery Group (SDG).

After DAT performed well for the Federal Creosote project, AOC worked with SMO to offer DAT to all USEPA Regions. DAT implementation was on a fast-track schedule, information was quickly gathered from the Regions to meet their specific presentation, style, and software needs. In August 1998, DAT was delivered to eight additional Regions.

Originally designed to meet Region II's needs, DAT was flexible enough to be redesigned to match any Region's systems. The tool produces reports and spreadsheets for each user but does not require the user to provide any additional software or hardware. Using a diverse staff and technical resources, AOC managed the development of DAT without interrupting normal CLP or SMO activities. AOC also provided Agency personnel with DAT orientation and training sessions. The sessions were designed to familiarize users with the tool, as well as identify potential implementation and use issues.

What is DAT?

The SMO contractor processes CLP data through an automated Data Assessment Tool (DAT), which is a complete data assessment package. This tool is used in the data assessment process for CLP deliverable packages from laboratories. Its features include:

- Incorporation of CCS and CADRE review to provide USEPA Regions with PC-compatible reports, spreadsheets, and electronic files;
- Spreadsheets delivered via Internet to the data reviewer within 24 hours of receipt of laboratory data;
- Customization of the technical requirements and report format (e.g. Data Base File, Lotus spreadsheets, etc.) to meet differing Regional needs;
- DAT reports are used as a tool in Regional data review and validation processes;
- Facilitation of the transfer of analytical data into Regional databases and programs; and
- CLP laboratories are provided with a data assessment report that documents any instances of noncompliance.

Data assessment does not conduct data validation and does not include determinations of data usability, qualification of data based on professional judgment, evaluation of data based on its intended use, or evaluation of compliance with site Quality Assurance Project Plan (QAPjP) and Sampling and Analysis Plan (SAP). The Regions are responsible for completing the data validation process before passing the data onto their customers (e.g. Regional Project Managers).

How does DAT Works?

As outlined in Figure 1, the five steps in the DAT process are:

1. Contracted laboratories provide analytical data electronically.
2. The electronic data is processed through CCS Initial Assessment (IA) checks to determine if the data is complete and in the proper format.
3. Laboratory electronic files that pass CCS IA, are processed using USEPA Mainframe to generate customized electronic spreadsheets and Data Base Files (DBF). These spreadsheet information is based on the laboratory qualified data. The results are forwarded to Regions via the CLP's Data Assessment Rapid Transmittal (DART) system, an Internet base E-mail system.
4. Files that pass CCS IA are loaded and processed through the CLP's data review and evaluation system.
5. The assessment results are processed using the USEPA mainframe to generate customized electronic files and spreadsheets. Results from the assessment process are generated in hard and soft copy. All files, spreadsheets/ DBF, and reports are electronically transmitted to clients via the CLP's DART.

Why use DAT?

DAT assesses and ensures that specified Superfund CLP data elements are present and adhere to contractual and technical Quality Control (QA) CLP specifications. Data derived from the DAT evaluation are used to support monitoring and decision making concerning CLP laboratory contracts, analytical methods, and program requirements. In addition, this data is used to generate routine and ad-hoc reports for CLP data users concerning laboratory performance, method performance, and

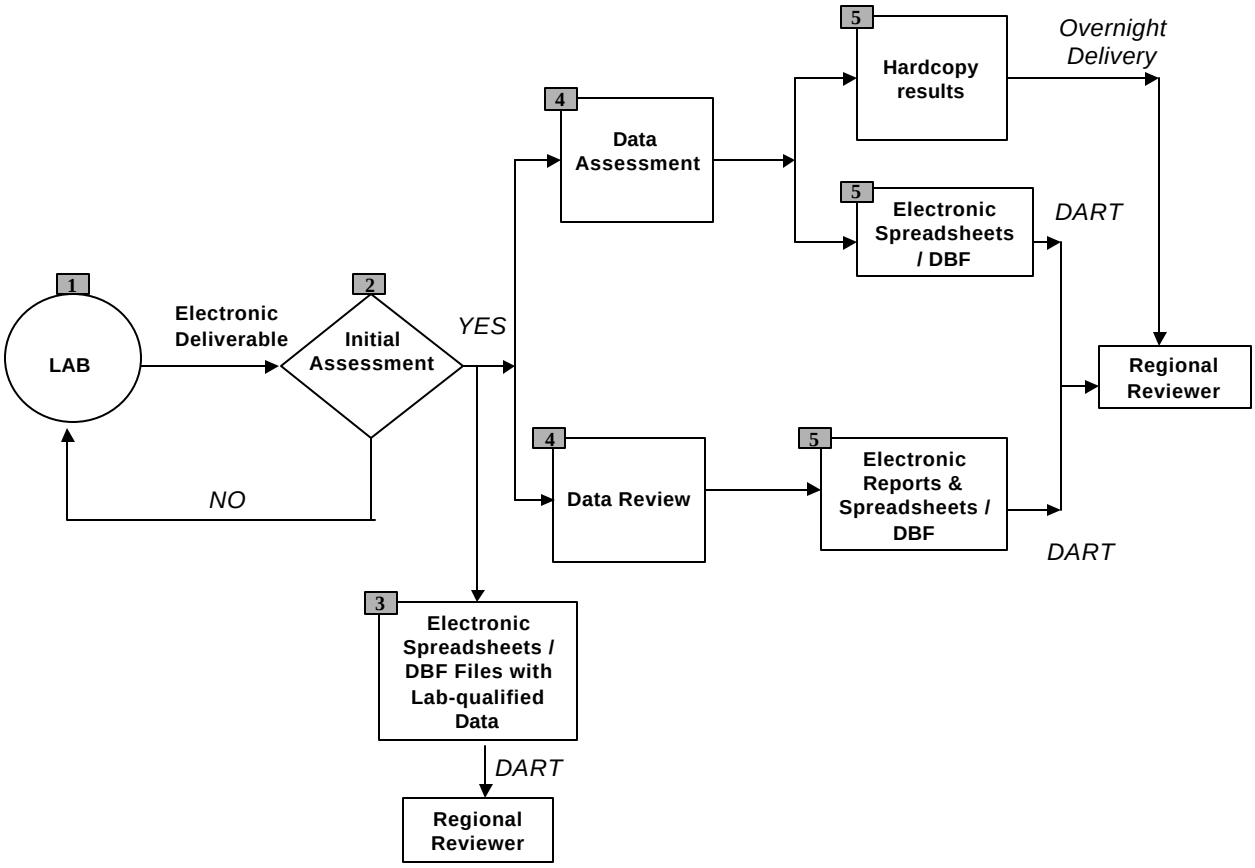

Figure 1. Data Assessment Process

contractual compliance. The DAT support systems provide a consistent set of review parameters – CCS – for each sample. The presence of this core of uniformity provides a valuable quality assurance tool to quantify a laboratory's performance and to support payment decisions.

DAT can be customized to meet the user's specific needs and requirements. The number and types of analytes for a variety of methods, and applicable criteria for data qualification (flagging) can be made Region-specific, and the output formats can likewise be customized.
Other benefits of DAT include:

- Assessment of contract compliance and quality control checks for over 3,500 organic and inorganic data quality parameters;
- Delivery of data into users hands weeks or months sooner than traditional review processes;
- Re-allocation of time saved on administrative activities to Regional data validation activities;
- Reduced manual data entry and duplicated keying and checking;
- Complete electronic CLP data assessment package, which can be passed on to Regional customers;
- No additional client software or hardware requirements;
- No client interaction required with USEPA's mainframe computer; and.

24 to 48 hours

- DAT utilizes DART – an active E-mail delivery system – for delivery of reports.

In addition to the attributes of product service to the customer, DAT has provided USEPA with substantial cost savings. Since the implementation of this service in August 1998, more than $2.7[a] million has been saved under the CLP's organic and inorganic programs.

DAT Users

This tool is currently used by nine of ten USEPA Regions. Several of the Regions have modified their data review process to better incorporate DAT into their day-to-day operations. Several USEPA Regions are using DAT results as the final data validation for 90% of their data and perform full manual data validation on the remaining 10%. The combination of manual and automated data review allows the Regions to gain and maintain a comfortable confidence level on accuracy of their DAT reports while meeting tight deadlines.

In addition to USEPA Regions, DAT is widely used by the Brownfields community. The tool provides quick data assessment with the appropriate level of Data Quality Objectives (DQOs), enabling the Brownfields community to respond to public needs quickly and efficiently. Since 1998 Brownfields' utilization of the CLP has increased by over 200 percent. This increase reflects the analysis of over 8,700 samples from the Brownfields sites through CLP. Twenty six (26) States have Brownfields activity supported by the CLP, over 70 sites during FY99 alone.

Conclusion

The use of CLP DAT ensures that the user has access to cost effective data of known and documented quality in the electronic file format required for mapping, modeling, and production of reports and spreadsheets within 24 to 48 hours of data receipt. CLP DAT is offered to all CLP customers. The tool assesses contract compliance and quality control checks for over 3,500 parameters and provides customized PC-compatible reports, spreadsheets, and electronic files via email directly to CLP customers. The electronic files facilitate the transfer of analytical data into CLP customers' databases, thereby eliminating manual data entry and errors caused by duplicated keying of information. DAT reports contain information at the site and sample level, listing all target compounds. For each target compound, the report lists concentrations found and the qualifier flag. Every customer of the CLP receives DAT reports.

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[a]This value was calculated by comparing the time it takes to manually validate data vs. the time it takes to perform this function using an electronic tool. For estimating purposes, it was assumed that organic data review takes 35 hours and manual inorganic data review takes 10 hours per SDG.

The Augmented Auditor--The Electronically Enhanced Assessor—Wearable Computers for Audits

By Paul Mills, Dave Paddock, and Ken Foreman (DynCorp, 2000 Edmund Halley Drive, Reston, VA 20191); and Peter Chapman (The Environmental Company, Inc., 2496 Old Ivy Road, Suite 300, Charlottesville, VA 22905)

Abstract: Traditionally, auditors ask questions and record the answers on paper checklists during an on-site visit. Days or weeks later, the answers are transcribed and formatted, then reports are printed and distributed to the auditee and client. But this entire process can be quickly changed, using newly available technology. This paper describes a combination of wearable computers, accessories and software applications that provide audit tools to make audits quick, easy, and more comprehensive. With instant access to a database of methods, checklists, and lab history, the auditor has the flexibility to expand and modify a planned assessment on-site. The auditor captures and records a variety of information, and produces a report before leaving the site. Wearing a tiny but powerful Xybernaut® computer and selected accessories that combine easy access and a variety of input options, the auditor can ask questions and record verbal responses as well as visual evidence. The auditor may dictate questions and record answers digitally. Or the auditor can type responses into the computer's hard drive on a miniature keyboard, or use a stylus and a pressure-sensitive screen for handwritten entries. Snapshots and moving video can be recorded using a head-mounted video camera. Video, sound, and other files can be transmitted to audit team members by infrared connections, and to off-site personnel through modem transfers. Using a head-mounted microphone, the auditor can easily add commentary to what is being recorded by camera or on the checklist. Instead of carrying a separate briefcase of the hardcopy versions of EPA methods, SOPs, and multi-volume QAPPs/FSPs/SAPs/HASPs, the auditor can store many checklists for a variety of topics (methods, surveys, old reports, problems, etc.) on the hard drive. New input can be added, and changes made at the site. New information can be compared to historical records. The "virtual audit" record will become increasingly important for those who weren't present at a particular assessment, but want to know as much as possible about the audited facility. Using the wearable computing system, an auditor or team could take pictures and record observations of the entire lab and its operations, edit in the observations made during the assessment for audited processes, show the equipment, personnel, and facilities, and provide commentary. If properly produced, the viewer would see more than just a passive videotape of an audit. It can be made interactive, with point-and-click capability for each lab area, instrument, person, test method, etc. Click on an instrument and see calibration and maintenance and run log records. Click on a person and see a resume, proficiency test results, PE sample performance, and training records. Click on an area of the lab, and see sample flow, testing types, backlogs, etc. Click on a method and see productivity, control charts, example reports, etc. The wearable computer system enhances the abilities of assessors to collect and report information about auditee capabilities and performance quickly and accurately. It

is easily operated, simple to maintain, and can pay for itself by reducing or eliminating traditional audit report processing steps.

The Need—How often does an auditor need a piece of information that he/she didn't bring on-site—it's back at the office? Wouldn't it be great to provide a completed audit report, complete with checklists, at the audit debriefing? Auditors on-site need quick access to lots of information—contracts, QAPPs, SOPs, audit checklists, audit plans, previous visit records, PE scores, correspondence—that can't all be carried in hardcopy. Making it available electronically, for easy viewing or printing, is an answer to auditors' needs. This paper describes the application of a wearable computer system as a valuable tool in the conduct of a laboratory audit. Results of the initial "proof of concept" pilot study are presented, and follow-up audit applications are planned.

The Answer—Wearable computers are small and lightweight, yet powerful and can be either touch- or voice-activated. This makes wearable computers perfect wherever it is necessary to perform multiple activities simultaneously, where work conditions are too fast-paced, cramped, or otherwise inaccessible for traditional computers. They are ideal for real-time monitoring of tasks that demand constant attention to ensure safety and effectiveness. Critical information can be viewed while performing the task, resulting in higher quality and output in a shorter time, improved safety, and reduced staffing needs. The advantages of the "heads-up, hands-free" operation of wearable PCs are that critical information can be viewed while performing the task, resulting in higher quality and output in a shorter time, improved safety, and reduced staffing needs. Wearable computers are now available to perform a wide range of tasks more easily, safely and efficiently than ever before, such as

- Accessing specifications while inspecting ongoing operations;
- Completing QA checklists while observing work in progress;
- Collecting data while on the move or in action;
- Following a video or computer-based training program while in the field;
- Conducting a facility inspection while walking around on-site.

Wearable PCs can be integrated into existing auditing systems so auditors can complete and file checklists and forms while on-site. The wearable computing platform incorporates wireless technologies to connect periodically or continually to an enterprise. E-mail can be sent and retrieved, as well as video feeds, from remote locations. The wearable computer and its configuration options are well-suited to provide and capture information that auditors need on-site, in real time. The accompanying table lists the equipment and specifications available for configuring a wearable system. It's like wearing a light desktop PC, but not as heavy or awkward.

Xybernaut Corporation is the leading provider of wearable computing hardware, software, and services. The company's patented wearable computer is a full-function Pentium PC that runs Microsoft MS-DOS®, Windows®, and Windows NT®, along with UNIX, Linux, and other operating systems that run on the Intel x86 architecture. The MA IV® model allows users hands-free access to information in the computer's internal storage, in local area networks and on the Internet on an as-needed, where-needed basis. Xybernaut's software is designed to provide users with the right

information when and where it's needed, using consistent navigation techniques and screen presentations. With the MA IV®, customers realize immediate savings in maintenance and repair, diagnosis, inspection, inventory control and data collection procedures. Xybernaut is headquartered in Fairfax, Virginia, with offices and subsidiaries in Germany and Japan. (Visit Xybernaut's web site at http://www.xybernaut.com.)

Connecting and configuring the Xybernaut Mobile Assistant IV® is easy. Just plug the battery holder's cable into the CPU's power port, and connect the XyberPanel™ flat-panel color display to the CPU's XyberPort. These connectors are designed for wearable use; they all lock into place so they won't slip out as you move around. The MA IV™ can also be used as a standard desktop computer. The Full Port Replicator attaches to the MA IV™ CPU, providing ports for attaching peripherals—such as a CRT desktop monitor, an MA IV™ 11" keyboard, a desktop mouse, and MA IV™ floppy diskette and CD-ROM drives. A PCMCIA network card allows connection to the local network. The Port Replicator has standard sound, parallel, serial, and USB ports.

Interface options in addition to the XyberPanel™ include: the XyberKey™ wrist-mounted keyboard used for entering text and numeric data in the field; the XyberView™ miniature, color VGA monitor mounted on a comfortable headset, suspended in front of the eye without obstructing vision (to the user's eye it appears the same as a 15 inch screen positioned 18 inches away); for hands-free operation, a microphone/earphone can be used to enter voice commands (this component also enables phone communication); the XyberCam™ head-mounted video camera can transmit real-time video images to a remote expert, or record to hard disk for later review, or provide on-the-job training. The computer can receive and send information by radio frequency (RF) Large Area Network (for ranges <1500 feet), by cell phone for medium-to-long ranges, and by satellite relay for specialized applications.

Pilot Study—Mr. Mills, the principal author, was retained as an independent consultant by The Environmental Company, Inc. to lead a pre-award audit of an environmental analytical laboratory for possible use at an environmental investigation. He teamed with the sponsor’s chemist, Peter Chapman. Peter was interested in seeing the Xybernaut® technology applied to lab audits, and the lab had no objection to its use. Mr. Paddock and Mr. Foreman at DynCorp entered the questions from five method-specific checklists developed by Mr. Mills into an Access database. They generated templates for asking questions/recording answers, and provided a quick run-through on the equipment and software setup and use. The following are observations from the audit that may be helpful in refining this application.

Battery Life—The equipment was unpacked and connected to make sure it would function properly for the next day's use. One battery was plugged into the hotel outlet to charge overnight. That battery was used for almost four hours before having to switch to the second battery. The second one didn't have a full charge, and was depleted in about two hours. Both were recharged that night, and during the next day after one was depleted it was set up to recharge for possible use four hours later, if needed. The audit was completed with the second battery still operative. Audit teams should travel with fully

charged batteries if possible, and recharge them at every opportunity. Smaller, lighter, longer-life batteries are desirable.

Software Applications—The checklist templates captured all the Yes/No/NA answers, using handwritten/keystroked input. The templates for each method were viewed in report form in Access, then exported from Access to Word as files for edits and printing. A temporary printing problem with the lab's laserjet printer was encountered, but resolved by a quick call to Dyncorp. The lab and the audit team appreciated the ready availability of these reports during the audit debriefing. Typically, the lab doesn't see them until the final report is sent, usually 2-4 weeks after the audit visit. There were other checklists and questions that could have been added after specific sample preparation methods were identified, but the auditor hadn't been trained to build new checklist templates. Audit team members should be trained to create new checklists, and add or edit questions to existing ones. This provides them flexibility to create questions and templates as needed for new topics and procedures.

Portability—The XyberPanel™ monitor input device was worn on the wrist, and the hard drive was carried in one lab coat pocket while either wearing the battery clipped to the belt, or in another coat pocket. With a keyboard and additional batteries added in other pockets, the numerous cables could be a safety problem unless wrapped/velcroed down. A backpack or chest harness would be helpful for carrying the equipment comfortably and for easiest access. The XyberPanel™ display was surprisingly readable, even with safety glasses on in bright light, and the stylus made it easy to navigate between programs, folders, and files.

Configuration—Using the wrist pad requires the auditor to "train" the SmartWriter™ to recognize his/her handwriting. Even with several training sessions, recognition was only about 50% accurate, especially poor when trying to write quickly. This is attributed to the limited number of training sessions, and the hasty way in which entries are often made to capture spoken responses. There were a few tactile problems with the stylus, with pointing and double-clicks requiring some practice. The keyboard was more accurate, but required two-hand use, or an empty benchtop to stabilize it. Stylus/keyboard input took the focus of attention away from the individual being queried, and the easy flow of question and answer was slowed. Future auditors could benefit from using voice-recognition software to record answers and comments. If the software can achieve >85% accuracy, this would be an improvement over the handwritten recognition accuracy. At least an hour is suggested for handwriting and speech recognition training time per user; more is better. Also, using a headset with a microphone and an eyepiece monitor instead of the wristpad will allow hands-free input for completion of forms. Configure and train on the particular setup to be used, to allow auditors to get comfortable and proficient with the apparatus.

Auditee Feedback—The lab personnel said: "Cute," "Is that Windows CE?" and "I want one." No intimidation factor was noted.

For the Future—It would be helpful to have a camera hooked up to take video and single-frame shots of the lab areas, documents, people, instrument configuration, etc. during different aspects of the audit. The Xybernaut® gear and audit checklists could be used in conjunction with IPIX®-type videos to

provide a complete CD-ROM package for auditors, and for customers of audits (regulators, potential clients). A virtual lab tour of each area, personnel, instrumentation, facilities, etc. could be prepared, with hyperlinks of lab audit questions to visual evidence and answers. Customers could get all the benefits of the audit, without the travel time and expense. Realtors do it now, why not labs? Followup and updates with individual clients could use video conferencing to examine a particular area or item in more detail, in real time.

Summary—The big advantages for applying the wearable computer solution to audits (field and lab) are: 1) Fast input and output--the old way was to write down answers, then later transcribe them into a finished report. If answers weren't complete, or notes couldn't be interpreted later, accuracy suffers. Now, the audit team can provide a complete report at the debriefing, allowing the lab staff to begin responding and taking corrective actions without waiting weeks for a final report. 2) Access to information. Instead of carrying a separate briefcase full of the hardcopy versions of USEPA methods, SOPs, and multi-volume QAPPs/FSPs/SAPs/HASPs, the auditor can package many checklists for a variety of topics (methods, surveys, old reports, problems, etc.) and have instant access to them on the hard drive. New input and changes can be added at the lab (by diskette or CD-ROM) and compared to historical records. 3) An audit team may use cell phones, video cameras, or radios to communicate and share information as needed immediately with off-site contacts.

Next Phase of Pilot Study—Additional audit templates, including more method-specific checklists, will be compiled and stored on the hard drive. These will include the draft NELAC checklists that are publicly available. At least one more lab audit, and/or field audit, is planned. These will provide additional opportunities for testing and refining the audit application, using voice-recognition and full-motion/still video input and head-mounted video display. The audits may also include the use of 360-degree video shots of the laboratory facilities. Hand-held and sheetfed scanners will be used to electronically record examples of lab documents. A progress report is planned for the WTQA2000 conference.

Acknowledgment—Thanks to The Environmental Company, Inc. for sponsoring the pilot study of the application of wearable computer equipment as part of the lab audit process. Thanks to Dyncorp for providing the equipment to Mentorprises Corporation and The Environmental Company, Inc. for this pilot study. Dyncorp is a marketing partner with Xybernaut, and Xybernaut equipment is listed on the Government Services Administration schedule. Contact Dave Paddock of Dyncorp at paddock@dyncorp.com for further information, a demonstration, or to configure a system for your needs.

COMPONENT	SPECIFICATIONS
CPU MODULE WITH XYBERPORTS™	Dimensions: 7.4 x 2.5 x 4.6in. (18.7 x 6.3 x 11.7 cm) Weight: approx. 1.9 lbs. (900 g) Processor: 200 or 233 MHz Intel Pentium®II MMX Memory: Up to 128 MB SDRAM Storage: Up to 6 GB internal removable HDD Self-contained, environmentally sound design Shock-mounted hard drive Magnesium alloy case Built-in mouse Built-in dual PC card readers (CardBus) Built-in sound card, full-duplex Ports for HMD/FPD, power, USB and replicator Full port replicator with microphone in, headphone out, line-in, serial, parallel, VGA, PS/2 Mouse, PS/2 keyboard and USB ports Miniport replicator (keyboard and FDD) Speech recognition engine included Choice of operating system included (Windows 95®, Windows 98®, Windows NT® and others)
HEAD-MOUNTED DISPLAY (HMD) XYBERVIEW™	Weight: approx. 1 lb. (470 g) 640 x 480 color VGA monocular Left- or right-side wearable Over- or under-viewable Microphone and ear-piece speaker Optional integrated miniature video camera, XyberCam™
FLAT-PANEL DISPLAY (FPD) XYBERPANEL™	Dimensions: 7.3 x 4.6 x 1.2 in (18.4 x 11.7 x 3.2 cm) 640 x 480 color VGA Built-in programmable buttons Pen or touch screen
BATTERY	Weight: 1 lb. (454 g) Lithium-ion (no memory effect) Rechargeable hundreds of times Up to 4 hours of battery life Combined AC power adapter/battery charger with protective circuitry Hot swappable—change batteries without shutting down applications

Never Audit Alone - The Case for Audit Teams

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On-site audits, conducted by technical and quality assurance (QA) experts at the data-gathering location, are the core of an effective QA program. However, inadequate resources for such audits are the bane of a QA program and, frequently, the proposed solution is to send only one auditor to the study site. There are several reasons why audits should be performed by more than one person:

***Safety** - Audits of EPA projects frequently involve hazardous chemicals or other environmental hazards. They also often involve working after normal work hours in remote locations with dangerous equipment. It is unsafe to work alone under such conditions.*

***Skills** - Many of EPA's projects are multidisciplinary, involving multiple measurement systems, several environmental media, and complex automated data collection and analysis systems. It is unlikely that one auditor would have the requisite skills to assess all of these operations.*

***Separateness** - Two auditors can provide two (sometimes differing) perspectives on problems encountered during an audit. Two auditors can provide complementary expertise and work experience. Two auditors can provide twice the surveillance power.*

***Support** - The operations that need to be assessed are sometimes in different parts of a site, requiring two auditing devices or considerable commuting time. Also, auditors are occasionally diverted by managers wishing to show their best efforts rather than the whole operation; if two auditors are on-site, one can interview managers while the other talks with technical staff. If there is a dispute, one auditor can support the other in verifying observations.*

***Savings** - Although sending one auditor is perceived to be a cost-saving measure, it may be more economical to send two auditors. Time on site (lodging, food) is decreased, more of the project is assessed in one visit, less pre-audit training is required, and report preparation is accelerated.*

In summary, sending more than one auditor on a field audit is smarter, safer, more effective, and can be less expensive in the long run.

INTRODUCTION

The only way to assess an environmental program without compromise is to perform on-site technical systems audits (TSAs) and performance evaluations (PEs) of measurement operations. Questionnaires, verbal communications, and mailed check samples always leave some doubt about the validity of the reported information. If one accepts the premise that on-site audits are necessary to evaluate an environmental study, then the next consideration is the best way to perform such audits. This paper addresses one aspect of optimizing audit procedures, the use of auditing teams instead of single auditors.

Lack of adequate resources – personnel, travel funds, equipment, audit materials – is often cited as a good reason to send only one auditor to assess an environmental field study. Although resources are often limited, the following discussion presents the case for using audit teams for improving the quality of assessments *and* for conserving the limited resources available for such audits. Case studies from the author's experience are cited to illustrate the advantages of using an audit team, and issues relating to safety, skill, separateness, support, and savings are discussed.

SAFETY

The standard for good laboratory practices and EPA health and safety guidelines recommend the "buddy system," in which no one person works alone in a hazardous environment. Even though appropriate safety precautions are followed and appropriate personal protection equipment is worn, there are often unexpected circumstances encountered in a research laboratory or in a field monitoring operation.

In addition to the potential hazards presented by the work environment, there are other considerations. An auditor became very ill with influenza on a recent on-site audit. Given that the audit had been planned as a team effort, the other auditor was able to assume most of the work and complete the audit within the allotted on-site time period.

SKILLS

Much of the work done or sponsored by EPA is multimedia and multidisciplinary. Few projects look only at the impact on one medium (water, air, soil), and few projects look at only the chemistry, toxicology, or engineering issues relating to a given environmental problem. Therefore, audits of current environmental studies often require expertise in several technical disciplines. Even though auditors are not expected to be technical experts in all of the projects that they assess, auditors should at least be familiar with the technical

terminology and the basic principles relating to an audited project.

A recent audit involved assessment of measurements of volatile organic compounds (VOCs) from a new, low-VOC technology for furniture finishes, under the auspices of the Environmental Technology Verification (ETV) Program. Auditors needed to assess the acceptability of the new finishes (durability, gloss, hardness), understand the manufacturing processes, assess the VOC emissions, and evaluate the relative toxicity of the new versus the older solvents. The audit team for this project consisted of an engineer with experience in air pollutant measurements, an analytical chemist, and a toxicologist/environmental chemist. The engineer provided assessments of the acceptability of the newer finishing processes. The analytical chemist prepared audit samples to evaluate the analysis of VOCs in air. The toxicologist/environmental chemist conducted the performance audits of three laboratories, evaluated the toxicity of alternative solvents, and briefed project managers and stakeholders on QA assessments of the project. Together, this audit team was able to assess the *overall* project and provide guidance on all aspects to the project managers.

Another field audit was performed by an environmental engineer and a chemist. This audit team evaluated a project that measured emissions of methane and other gases from a waste lagoon at a meat processing plant. A relatively new measurement technique, Open-Path Fourier-Transform Infrared (FTIR) spectrometry, was being used to measure the gases. In FTIR, an infrared beam is sent across the plume, downwind of the lagoon. The chemist, an expert in FTIR measurements, assessed the instrumentation and procedures, and found that the FTIR system was being operated correctly. The environmental engineer was concurrently observing real-time measurements and noticed that concentrations of methane decreased very rapidly with small shifts in wind direction. The engineer called the local weather bureau to obtain wind direction information for that day and purchased a compass from a local store. He determined that, although the very complicated FTIR measurements met data quality specifications, the wind direction measurements were inaccurate by more than 30 degrees, so that only a small portion of the plume was within the infrared beam part of the time. The engineer assisted the field crew in correcting the wind direction measurements so that valid data could be collected for the remainder of the project.

SEPARATENESS

An audit team of several individuals increases the number of eyes on the problem. An audit team provides at least two perspectives on problems encountered. An audit team often provides different educational backgrounds and differing work experience to assist in problem solving.

A recent project involved the testing of several new automated instruments for the measurement of metals in combustion emissions. To assess these new instruments, sampling using each new instrument was performed concurrently with the EPA reference method, Method 0060, which requires collection of a sample for subsequent analysis in a

laboratory by atomic absorption spectrophotometry or other methods. Two analytical laboratories were assessed for their ability to analyze the metals of interest by the reference method, to allow EPA to have confidence in the reference method results. Two auditors, a chemist and a QA specialist, performed a TSA and PE at the two laboratories. The TSA showed that one laboratory had superior training records and facilities. However, when the PE results became available, the laboratory with the good training records and facilities did very poorly on analysis. It seems that the laboratory with the good facilities did not assign one person to review all sample-related data, providing different teams to do analysis, data reduction, and validation. Even though the arithmetic was correct, no one had noticed that the reagent blank samples gave negative values. All sample analysis values were too low. The chemist was able to spot the problem in data reduction and provide constructive comments on correcting the analytical problem.

SUPPORT

Two auditors can assess two different operations at the same site, interface with managers more efficiently, and verify each other's observations.

In a recent audit at a Chlor-Alkali production plant, a team of two auditors was able to perform TSAs of nine different measurement systems in two days. This was done by careful preparation of audit checklists, thoughtful division of the work, and assignment of primary assessment duties for each system to the more knowledgeable person, with the other auditor taking notes. In this way, all systems could be observed and assessed in the allotted time period. Each auditor then verified the other's observations.

Another field audit was performed at a pilot plant built to demonstrate adsorption and destruction of the VOCs emitted from paint spray booths. This large-scale operation had been constructed by another government agency, and EPA was asked to evaluate its operation. When the two auditors arrived on-site for a 2-day TSA, they were greeted by the manager of the pilot plant, who insisted that they accompany him on an extended tour of the facility. After half of the first day on site, the manager was still talking and touring. One auditor was able to leave the tour and begin to assess the process by questioning technicians running the equipment. The other auditor continued to accompany the plant manager, collecting process information.

SAVINGS

Savings from the use of audit teams come with careful planning and division of work, resulting in less time on site. Savings accrue from "doing it right the first time" without the need to repeat field audits, with the accompanying doubling of travel and per diem costs. If an audit is worth doing and if it provides a "value added" to a project, then the increase in the accuracy and detail in the information collected by a team rather than one auditor can be

considered a cost benefit. In addition, an audit team of persons with diverse technical skills decreases the pre-audit training time and increases efficiency on site. The time needed to prepare the final audit report is also decreased.

OPTIMAL AUDIT TEAM COMPOSITION

Given the advantages of audit teams, the question remains as to the best audit team composition. In the author's experience, the following sorts of teams have led to productive and successful audits:

- QA expert and EPA project officer/technical expert
- QA expert and technical expert (contractor or EPA employee)
- Engineer and chemist (for chemical compound measurements at an engineering demonstration site)
- Physicist and chemist (for evaluations of measurement instrumentation)

Conclusion

Using the team approach for audits of field studies has been shown to enhance safety, provide the necessary skills, contribute multiple solutions to problems encountered, furnish effective support, and result in overall savings.

Development of FORMS II Lite 4.0: A Rapid Prototype Approach

Environmental Information Quality Session

Presented by Dana Tulis, Director, AOC, OERR
and Meghan Zimmerman, DynCorp

USEPA's OERR Analytical Operations/Data Quality Center (AOC), recently developed and released a new software system that enables samplers to electronically capture sample information in the field. The Field Operations and Reporting Management System II Lite (FORMS II Lite) 4.0 software, which is used on lap-top computers, can be used to track all Superfund samples (i.e., Contract Laboratory (CLP), non-CLP, and field analytical). With FORMS II Lite, samplers enter sample information once into the software system for multiple uses. The software allows samplers to generate sample-specific identification numbers and automates printing of sample documentation in the field (e.g, traffic reports, bottle labels). It also facilitates the electronic capture and transfer of sample information into Regional databases and gives Regions a user-friendly solution for tracking the destination of Superfund samples to laboratories.

FORMS II Lite is an efficient system for tracking the destination of samples to laboratories. It helps users quickly determine site problems or potentially fraudulent laboratories. It also solves a number of quality assurance (QA) problems associated with handwritten paperwork and determining the ultimate destination of samples. For the Superfund program, there is a great deal of documentation associated with sample collection that must be maintained throughout the sampling process to ensure sample integrity and successful litigation with responsible parties. Prior to FORMS II Lite, sample documentation was handwritten, making the in-field paperwork process tedious, time consuming, and cumbersome. Handwritten documentation led to a number of errors (such as laboratories wrongly interpreting information about a sample), additional work (manual data entry for multiple uses such as sample tags, labels, chain-of-custody reports, Regional databases), and problems with litigation.

This paper describes the challenges of addressing the QA problems that AOC needed to solve and the process for developing and implementing FORMS II Lite 4.0.

INTRODUCTION

The collection of hazardous waste samples requires a large amount of supporting documentation in order to ensure sample integrity. Although the completion of this handwritten documentation is necessary for

clean-up and litigation of hazardous waste sites, the process is laborious and time consuming. For example, 10 volatile water samples may have up to 75 pieces of associated sample documentation, including sample labels, sample tags, custody seals, traffic reports, and chain-of-custody records. This extensive amount of handwritten paperwork can cause a number of errors and result in problems with data quality.

Sample documentation involves a considerable amount of information overlap. Sample tag labels, bottle labels, traffic reports, and chain-of-custody records often contain the same information. Repeated handwritten documentation of the sample information slows the sampling process and fatigues samplers. In addition, manually completed information frequently results in errors such as laboratory misinterpretation of sample information. This problem may delay sample analysis and can often lead to missed holding times.

Illegible handwriting on the traffic report also causes a delay for the end user of the data. During fiscal year 1999, over 2,800 shipments of 837 cases containing approximately 40,000[a] field samples were shipped to CLP laboratories. Approximately 33 percent[b] of the cases included at least one incident associated with problem paperwork, including discrepancies between sample tags, sample bottles, and the traffic report; mislabeled Performance Evaluation (PE) samples; and illegible handwriting on the traffic report. Although the documentation is intended to maintain sample integrity, these errors ultimately weaken the evidential nature of the analyses. Further, these problems can influence the potential litigation of the site.

AOC determined that it needed a two-fold solution to address these QA issues. The first solution included additional training for samplers who generate the paperwork. An updated Sampler's Guide would enhance already implemented procedures. The second part of the solution was more complex. It involved the development of an automated tool to assist the samplers. The challenge in creating an automated tool was determining how to develop a product that was user-friendly and could accommodate the needs of a national audience. AOC also wanted to develop a tool that would be useful for all Superfund laboratory and field samples, not just limited to the CLP.

Background

To identify possible solutions to the quality assurance problem, AOC directed SMO to investigate existing software solutions. This included a product called FORMS that was used by Region 4, and Sample Track™ that was used by several contractors within Region 10. While these systems were effective, they were both DOS-based and not easy to customize to the individual needs of the users.

In 1996, existing efforts were initiated to come up with an enterprise solution called FORMS II; however, implementation was marred by the lack of existing infrastructure to support the solution. Several on-site visits were conducted in the Spring of 1998 to evaluate and validate processes conducted by field samplers

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[a] This number represents the actual number of samples shipped, not the number of samples analyzed. During fiscal year 1999, 51,739 samples were processed through the CLP.

[b] This number was calculated based on the Case Incident Report generated by DynCorp, AOC's Sample Management Office (SMO).

for the collection and documentation of environmental samples. In July 1998, AOC identified the need for a stand-alone portable software system that could be operated from a notebook computer by users with little or no computer experience. FORMS II Lite – which simplifies the sample documentation process – was developed by SMO with AOC to assist samplers with documenting the collection of water, soil, and air samples.

What is FORMS II Lite?

FORMS II Lite is designed to automate many of the procedures associated with sample documentation that must be followed to assure data quality. The software ultimately generates sample tags, bottle labels, traffic reports, chain-of-custody records, and facilitates electronic capture of information into other databases. It also tracks the samples from collection in the field to delivery at the laboratory. FORMS II Lite is designed in a Wizard format that takes the user through an eight-step process associated with the following information:

- Site and project
- Members of the sampling team
- Sample analysis types
- Collection location, date and time, and sample matrix
- Sample and tag numbers
- Laboratories receiving samples
- Sample shipments
- Traffic Report customization

The software allows the user to customize data entry screens throughout the entire documentation process. Additionally, users can customize the format and content of sample labels and sample tags based on specific requirements. FORMS II Lite can be used to document and track all Superfund samples (e.g., CLP, non-CLP, and field analytical) shipped to EPA Regions, states, and CLP or other commercial laboratories.

THE RAPID PROTOTYPING DEVELOPMENTAL PROCESS

A rapid prototyping approach was used to develop FORMS II Lite. AOC directed SMO to develop a software that could perform the basic functions and then make modifications based on user feedback. The challenge involved designing the software to incorporate specific requirements of the 10 different EPA Regions while maintaining a simple product that could be adapted by several users.

Development of FORMS II Lite Beta 1.0

- In November 1998, Beta 1.0 was released for evaluation by several Regional users. The software was also tested at a Region 4 Superfund site where it was run in parallel to the FORMS software.

- Although many issues were addressed as a result of the feedback from using Beta 1.0, focus was placed on the effectiveness of assigning sample numbers and printing tags.

Development of FORMS II Lite Beta 2.0

- After incorporating feedback gained from the first release, Beta 2.0 was developed and tested on-site in March 1999.
- The software performance had improved since Beta 1.0, but additional changes were still needed enhance usability. These changes included the addition of user interfaces to provide quality control of the data entered by the user and the ability to export data from the software to other databases.

Development of Beta 2.1

- In May 1999, Beta 2.1 was released to all 10 USEPA Regions and 14 states. Feedback from such a broad range of users was necessary for software improvement. This release allowed AOC to address specific needs of various Regions and obtain evaluations from several state users.
- As a result of the release of Beta 2.1, AOC determined that the software needed to be more flexible to accommodate the needs of many users. While the focus was made on the stability of the software, additional customization of user interfaces and the ability to use FORMS II Lite on Windows NT was also developed.

Development of Beta 3.0

- Comments and feedback were collected, and a limited distribution of Beta 3.0 was released in September 1999. The intention of this release was to use the software on-site during the sampling event without technical support.
- Feedback from this release included defaults for accelerated data entry.

Release of FORMS II Lite 4.0

These last comments were incorporated into the final release of FORMS II Lite 4.0 in February 2000. Version 4.0 was then distributed to all 10 Regions (Regional Sample Control Center Coordinators), 13 states, and the Bureau of Reclamation. Version 4.0 is currently being actively used by Regions 3, 4, 5, 6,and 10 for specific projects. AOC is providing hands-on training to the majority of the Regions for future use. The feedback from CLP laboratories and other users has been positive. Future plans for the software include adding more flexibility in customizing user interfaces and further developing the use of electronic data for multiple uses.

The following is an example of FORMS II Lite training that took place in Calcasieu Estuary, Calcasieu Parish, Louisiana.

CASE STUDY

For Regions that are extremely busy, AOC attends actual sampling events to demonstrate the software.

Background

A remedial investigation/feasibility study for the EPA is being conducted on the Bayou d'Inde within Calcasieu Estuary, Calcasieu Parish, Louisiana. The study includes the investigation of organic and inorganic chemical contamination, including human health and ecological risk assessment. Chemical

contamination, mainly from industrial discharges of local industrial activities of facilities adjacent to the bayou has been detected in surface water, sediment, fish, and crustacea in the Bayou d'Inde area.

Challenges

Due to the 800 samples scheduled for the Calcasieu site, the users requested on-site training of FORMS II Lite. The general procedures for completing the handwritten paperwork involved completing the sample tag and chain-of-custody documentation as the samplers called in information from the field.

FORMS II Lite was run in parallel to the manual transcription procedures. Two sample coordinators shared the responsibility of completing the documentation. One sample coordinator entered the sampling information into the FORMS II Lite database while the other continued to handwrite the documentation. As a result of having already entered the sample numbers into FORMS II Lite, the sample coordinator using the software could quickly assign the type of analysis to a sample number. After all the samples were collected, this coordinator was able to automatically generate sample tags, sample labels, and chain-of-custody records for the samples.

Feedback

The sample coordinators offered positive feedback about the QA steps that were implemented in the software. They were able to see the data they had entered in a spreadsheet format, which allowed them to review their work before the documentation was generated. Other comments included relief from unorganized paperwork that was scattered in the trailer as the samplers called in sampling information.

After running FORMS II Lite in parallel to the handwritten procedures, the sample coordinators discovered that using the software during their sampling activities saved approximately 10 to 15 minutes of work per sample. Based on the average number of samples collected per day at the site, FORMS II Lite saved approximately four (4) labor hours per day, thereby reducing labor hours by 50 percent and increasing productivity by 100 percent. At the 800-sample project level, 200 labor hours (25 working days) were saved.

BENEFITS OF FORMS II LITE

FORMS II Lite was designed to resolve QA issues associated with sample documentation. With FORMS II Lite, sampling information is entered once and then used to generate sample tag labels, sample bottle labels, traffic reports, and chain-of-custody records. The software can also export the electronic data associated with the sampling activity into the laboratory or Regional office database. It simplifies and accelerates the sample documentation process by reducing the generation of handwritten documents by over 70 percent[c].

[c] This estimate was based on the ability of FORMS II Lite to eliminate the manual transcription of the sample tags, sample labels, and the chain-of-custody, three out of the four main pieces required by CLP.

As a result, FORMS II Lite minimizes errors made by the sampler, by the laboratory, and the end user. This error reduction improves the quality of the data and its supporting documentation. FORMS II Lite also reduces the time and effort spent in the field completing complex sample documentation. This allows technical staff to spend more time on sample planning and collection activities in an effort to better manage the sampling event.

Another significant feature of FORMS II Lite is that it ensures that samples are tracked electronically from the point of collection to the time of delivery to the laboratory. As a result, information captured by FORMS II Lite can be incorporated into existing tracking systems, thereby allowing the capability to detect site problems or potentially fraudulent laboratories. Although the software is flexible enough to accommodate multiple users, it maintains integrity of the sampling activities because of built-in QA features. For example, the software generates sample-specific CLP compliant identification numbers and will automatically increment the sample numbers.

CONCLUSION

The relatively quick implementation of FORMS II Lite resulted from being able to utilize the users' knowledge base. AOC understood the effects of problems associated with paperwork, i.e., problems including potential impact on the integrity of samples and a general delay in the sampling process. The rapid prototype approach was successful because the software was designed as a simple tool and incorporated the needs of the user. The resulting development of the rapid prototype approach, FORMS II Lite, resolves many of the problems associated with sample documentation. The software greatly reduces the amount of paperwork required, reduces the occurrences of error in the paperwork, and significantly reduces the amount of time spent completing the paperwork.

Future steps toward improving FORMS II Lite will revolve around the keeping the software simple and user-friendly. Modifications will be based upon new client requirements.

Using Data Management to Improve Data Quality

Authors: Hilary Price, Jeffrey Sabol

This paper describes how to develop an organization-wide data management plan that improves data quality and usability on environmental monitoring projects of all sizes. The suggested techniques are based on experience designing, developing, and implementing a data management approach, database, and software for the Lake Michigan Mass Balance study, the largest freshwater pollutant dynamic assessment ever attempted. Necessary quality assurance procedures are described for an organization's approach to data collection, transfer, and maintenance. Topics addressed include how to develop a data management approach, reduce the frequency of data errors, and document data quality in ways that safeguard the longevity and reusability of data investments.

In 1993, the Great Lakes National Program Office (GLNPO) undertook an extensive study to monitor the transport and fate of contaminants in Lake Michigan. Known as the Lake Michigan Mass Balance (LMMB) Study, this multi-million dollar project was one of the largest ambient monitoring efforts ever undertaken by EPA. Being a true multi-media study, environmental samples were collected from tributary waters, lake waters, biological species, the atmosphere, soils, and sediments in an attempt to characterize pollutant dynamics in one of the most complex freshwater systems in the world. Analytical results from these samples were used to characterize the current state of the lake ecosystem and to develop models of pollutant dynamics and contaminant cycling.

To prepare for the LMMB study, GLNPO and American Management Systems (AMS) developed a data management approach to coordinate data exchange, avoid duplication or effort, ensure cross-project utility and long-term value of data, and improve data quality on all of GLNPO's monitoring projects. The data management techniques described in this paper are based on experience designing and developing GLNPO's office-wide data management approach and implementing it on the LMMB study. The techniques are derived both from successful elements of the approach and from lessons learned during the LMMB study. Designed to be flexible and scalable, these techniques can be implemented within any organization to improve the quality and usability of data on monitoring projects of all sizes.

Data Quality

"Data quality is a state or condition that can be measured. Generally speaking, it is the ability of data and derived information to meet requirements related to business objectives, and meet them in an efficient manner" (W.E. Deming). A successful data management approach can dramatically improve data quality if it is designed with an organization's quality objectives in mind. Specifically, the approach should include methods for addressing each quality objective. While data management alone cannot ensure that all quality objectives are met, ignoring quality objectives in the data management approach is a sure way to fall short of those goals.

The first step toward developing an effective data management approach is to define data quality objectives. Two types of data quality objectives are typically used: 1) primary use quality objectives, and 2) secondary use (re-use) quality objectives.

Primary use quality objectives are defined at two levels: project-level objectives and organization-level objectives. Project-level objectives are based on the intended use of the data, vary from project to project, and are typically described in terms of statistical measurements of data quality, including precision, accuracy, representativeness, comparability, completeness, and sensitivity. Organization-level objectives are based on cross-project goals such as reducing the incidence of data reporting errors or ensuring adherence to QA plans. The data management techniques discussed in this paper address cross-cutting, organization-level objectives and should be implemented on all projects. Customized data management techniques that address project-level objectives should be developed during the planning phase of a project and implemented in conjunction with the organization-level techniques described in this paper.

Secondary use quality objectives relate to the longevity and reusability of data. The purpose of secondary use quality objectives is to maximize the return on an organization's investment in data collection by ensuring that data remain usable long after the study for which they are originally collected. For example, GLNPO implemented a secondary use quality objective known as the 10-year rule, which specified that data should still be re-usable ten years after the collection effort, with minimal involvement from the original participants of the study. This paper provides techniques for improving data quality for secondary use, including the storage of extensive contextual data and objective quality indicators.

Data Management

This paper describes data management techniques for a successful organization-wide data management approach. The elements are organized according to their occurrence in the project life cycle. Each section describes key data management considerations and includes a table indicating who should be responsible for data management responsibilities during each phase of a project. Although numerous types of activities must be conducted in order for a project to be a success, this paper focuses only on those activities within the realm of data management.

Participants

The first step toward developing a successful data management approach is to make sure the right people are involved in developing that approach. This section identifies several key groups that must participate in the development of the data management approach in order for the approach to be a success. Although each of the groups listed below will play roles in many aspects of a project, only those roles related to data management activities are described below. The same people may play multiple roles as long as each role is filled.

Data Management Team - The data management team is responsible for developing and documenting the data management approach, providing and maintaining tools for data collection, transfer, and storage, and providing training and standard operating procedures for data reporting. The

data management team is also responsible for identifying data management tactics that can improve data quality for primary and secondary use. This team should consist of individuals with expertise in environmental monitoring and technology, including the database administrator, data manager, and software/database development team.

Quality Control Team - The quality control team is responsible for developing data quality objectives, identifying data management tactics that can improve data quality for primary use, and measuring the quality of submitted data using statistics. This team should consist of individuals with expertise in quality assurance and environmental monitoring.

Data Collection Team - The data collection team is responsible for collecting, recording, and submitting high-quality data. This team should provide feedback to the data management team regarding the usability of the data collection tools.

Primary User Team - The primary user team is responsible for informing the data management and quality control teams of their data needs, desired output formats, and time line.

Project Management Team(s) - The project management team is responsible for the coordination and oversight of the other teams and must ensure that all data management activities receive adequate funding. This team should consist of individuals from the quality control, data management, data collection, and primary user teams as well as the individuals from the sponsoring organization who are responsible for funding and managing the project.

Planning

The planning phase is the most important phase of any study. Mistakes made during this phase are propagated through each subsequent phase of the project, which can have a dramatic negative impact on the project's deadlines and budget. Planning phase responsibilities include:

Team	Responsibilities
Data Management Team	• Develop the data management plan and disseminate it to project participants • Identify or develop the data collection software and data repository • Provide SOPs/training sessions to the data collection team • Participate in status meetings and problem-solving sessions
Quality Control Team	• Determine the quality objectives • Suggest ways to meet quality objectives through data management • Review the data management plan • Participate in status meetings and problem-solving sessions
Data Collection Team	• Provide information on available technologies, data reporting preferences, etc. • Attend training sessions • Provide feedback on data collection tools • Participate in status meetings and problem-solving sessions
Primary User Team	• Determine data output elements/formats needed for models • Review quality objectives to ensure the data will meet their needs • Suggest ways to meet quality objectives through data management • Participate in status meetings and problem-solving sessions
Management Team	• Establish, oversee, and coordinate other teams • Provide adequate funding for all data management activities • Initiate and oversee frequent reviews of all planning-phase products • Participate in status meetings and problem-solving sessions

The following data management techniques should be applied during the planning phase:

Incorporate lessons learned from past projects - One of the most effective ways to ensure that a data management plan will produce high quality data is to review data quality problems encountered on other projects. Activities such as talking to study participants, reviewing project literature and lessons learned, and reviewing data from other projects will highlight problems other projects have experienced that may be avoided through effective data management.

Integrate teams early - A successful data management plan should address the data quality objectives and the needs of the primary users. Additionally, the plan should present solutions that are feasible for the data collection team. To ensure that the data management plan fits all of these criteria, all project participants will need to work closely together from the start of the project. Waiting until later in the project to integrate the teams is likely to result in a substantial amount of rework to the data management plan and a delay in the completion of the planning phase.

Document and disseminate the data management plan - The data management team should develop and disseminate a data management plan with sections addressing the following topics:

Data flow pathways - Data flow pathways describe the order in which data move between project participants and the roles and responsibilities of the project participants during each phase of the project. The data flow pathways should be described in detail in the data management plan to inform project participants about their responsibilities on the project.

Collection tools and interim storage/transfer mechanisms - Data collection tools can be used to ensure that data are reported consistently and minimize data errors. The data management plan should describe all data collection tools that will be used on the project. Data collection tools are discussed in further detail in the Data Collection section of this document.

Data standards - Implementing data standards helps to ensure that data can easily be compared. For example, if the primary users want to look at chemical concentrations by depth, a measurement standard may be implemented so that all depths are reported using the same units. The data management plan should describe all data standards that will be used by the project including naming conventions for samples, files, and database structures, data reporting formats and requirements, and measurement standards.

Final storage location - The final storage location is the database where the data will ultimately reside. The data management plan should indicate what the final storage location for the data will be and how the data will be moved into the final storage location. Requirements for the final storage location are discussed in further detail in the Data Storage section of this document.

Output formats - The data management plan should describe any output formats that the primary users or quality assurance team will need to receive data in. The purpose of including output formats in the data management plan is to verify that all data required by the primary users or the QA team is gathered during the data collection and reporting process.

Change control procedures - The data management plan should describe the steps for changing or resubmitting data. These steps include version tracking procedures, data flow pathways for re-submittal, and a description of how changes will be handled within the final storage location.

Provide standard operating procedures and training - Standard operating procedures and training sessions ensure that the data collection team understands its role in the data collection process as well as how to use the data collection tools.

Conduct frequent reviews - Frequent reviews ensure that all teams are on track to complete their responsibilities in a timely manner. They also provide a means for identifying issues such as designs that do not meet project needs.

Data Collection

Many of the quality assurance problems typically encountered on environmental monitoring projects, including data-entry errors, data inconsistencies, and missing data, have their roots in the data collection phase. These problems can often be eliminated or minimized through the use of data collection tools. On the LMMB study, GLNPO required data to be reported in a standard format, which improved comparability between data sets by enforcing consistency. For future studies, GLNPO is developing an automated data collection tool that not only enforces consistency but also checks for errors as the data are entered and/or reported.

This section describes data management techniques that can be implemented during the data collection phase of a project to improve data quality. These techniques can be built into an organization's data collection software to ensure that they are implemented across all of that organization's projects. To guarantee the longevity and success of the software, care should be taken to ensure that the collection tools are compatible with the final storage location, capture all data required by the primary users, and allow users to report data quickly and easily. To maximize the return on an organization's investment in software, data collection applications should be designed for organization-wide use rather than for a single project. If new data collection software must be built, it should be done during the planning phase of the project.

Data collection phase responsibilities include:

Team	Responsibilities
Data Management Team	• Ensure that the data management plan is being followed • Review early data submissions and provide feedback to other teams • Participate in status meetings and problem-solving sessions
Quality Control Team	• Suggest data management changes to address data issues • Participate in status meetings and problem-solving sessions
Data Collection Team	• Collect data, adhering to data management approach • Ensure that data is as error proof as possible • Participate in status meetings and problem-solving sessions
Primary User Team	• Review early data submissions to ensure the data meets their needs • Participate in status meetings and problem-solving sessions
Project Management Team	• Ensure follow-up of all issues • Participate in status meetings and problem-solving sessions

The following techniques should be applied during the data collection phase of a project:

Avoid duplication of data reporting - Avoiding duplication of data reporting will not only speed up the data reporting process but will also reduce the frequency of conflicts between data sets. For example, if ten samples are collected during a single visit, the visit's header information should only be reported once rather than ten times.

Reduce data reporting errors through reference values and pick lists - Providing lists of well-defined reference values will ensure that all samples and results are described using the same language. This prevents a data user from having to guess, for example, whether 'composite' in one data set means the same as 'composite' in another data set. In customized data-entry software, the use of pick lists can solve problems such as mismatched samples and results by forcing the user to pick from a list of valid values.

Ease the data-reporting burden through the use of defaults - Storing extensive metadata improves data quality by providing context to secondary data users. Reporting extensive metadata, however, can seem tedious and time-consuming to the data collection team. Allowing the data

collection team to specify and save sets of default values for data elements is one way to reduce the data-reporting burden while still capturing valuable metadata. For example, a team that is collecting only sediment samples could specify sediment as the default sample medium. The value 'sediment' would then be applied as the medium for each sample that team reports. Future data users would be able to see that the samples were sediment samples, but the data collection team would not have to record 'sediment' for every sample.

Move error checking as close to data collection as possible - Data errors become more expensive and difficult to fix the longer they exist without being caught. Tracking down members of the data collection team, who may no longer work for the same organizations they did at the time of the study, and may no longer have time to answer questions once their grant money has run out, can be a time-consuming, expensive, and frustrating endeavor. Even in cases where the person who provided data is available to answer questions, the chances are slim of that individual remembering the real pH for a sample with a reported pH of 22. Seconds spent correcting a keypunch error during data entry may save hours of the quality assurance team trying to fix that same keypunch error a year later. Using error-checking software to detect errors at the point of data entry can drastically reduce the cost of producing high quality data.

Check the data for completeness before submission - Completeness checks prior to data submission can alert the data collection team to deviations from the project's quality assurance plan. For example, if a quality assurance plan called for one field duplicate to be collected at every station, the data collection software could perform a completeness check to make sure one or more field duplicates were reported for each station. The software program would then alert the data collection team if any field duplicates were missing from the data set.

Review data early - Reviewing data early in the data collection effort will alert the data management and quality assurance teams to any problems with the data. These problems can then be corrected in time for data collected later in the study to benefit from the correction.

Data Transfer

The data transfer phase is when data are transferred from the data collection team to their main repository. Data collection software may include automated procedures for transferring data to the main data repository. If the data transfer will be performed manually, detailed procedures for transferring the data should be described in the data management plan. Transfer phase responsibilities include:

Team	Responsibilities
Data Management Team	• Answer questions/address issues related to data transfer • Participate in status meetings and problem-solving sessions
Quality Control Team	• Participate in status meetings and problem-solving sessions
Data Collection Team	• Submit data to the appropriate parties • Participate in status meetings and problem-solving sessions
Primary User Team	• Participate in status meetings and problem-solving sessions
Project Management Team	• Track data submissions • Participate in status meetings and problem-solving sessions

The following suggestions should be considered during the data transfer phase of the project:

Avoid re-entry of data - Re-entering or re-formatting data introduces opportunity for data errors to appear. A sound data management plan should not call for data to be re-entered or re-formatted at any point, except for when data are transferred from handwritten field or lab sheets to electronic form or when reformatting is done after the data has reached its main repository.

Avoid passing data through multiple systems - Passing data through multiple systems before sending it to its main repository also increases the probability of data errors. Additionally, moving data through multiple systems will increase the costs associated with changes to the data format, as multiple systems will need to be modified to accommodate the changes. Instead of passing data through multiple systems, the data should be sent directly to the main repository, from which it can easily be extracted and sent to other systems for analysis.

Data Storage

Data storage extends from the data transfer phase until the data ceases to be available for use or re-use.

Storage phase responsibilities include:

Team	Responsibilities
Data Management Team	Maintain the data storage location Ensure continued access to the data Participate in status meetings and problem-solving sessions
Quality Control Team	Add quality indicators to the data (e.g., statistics, summaries) Participate in status meetings and problem-solving sessions
Data Collection Team	Participate in status meetings and problem-solving sessions
Primary User Team	Retrieve data from the final storage location Participate in status meetings and problem-solving sessions
Project Management Team	Provide support for data storage location (e.g., db support, etc.) Participate in status meetings and problem-solving sessions

Consider the following suggestions when selecting the main data repository:

Choose a data repository that is likely to persist - In order for data to be reusable, it must be accessible. Choosing a database technology that is on the decline or developing a single-project database is likely to limit data access in the future. In order to ensure that data remain available, care should be given to selecting an established, well-funded database and database technology.

Store all data in a single repository - Storing all data in a single repository will minimize the costs associated with maintaining data accessibility. Additionally, it improves the chance that the repository will not go away. Finally, data that are stored in a single location are easier for users to access and, therefore, more likely to be used.

Choose a main data repository that is easy to access and update - Using a relational database as the main repository will ensure that the data are stored efficiently and are easy to access.

Relational databases also make updates easier because they do not store multiple copies of the data, so updates will only need to be made in one place.

Only store data of documented, measurable quality - Only data of documented, measurable quality should be stored in the main repository. Subjective data quality descriptors such as "good" or "excellent" mean little to potential data users. On the LMMB study, a three tiered, objective approach to documenting quality was implemented. At the first tier, project-level information such as study abstracts and bibliographic references were stored in the database. The second tier included method-level information such as methods and equipment calibration data. This third tier included result-level qualifiers such as detection limits and analyst/QC officer comments. Together, these three tiers of metadata provide extensive information about data quality that potential users can use to determine the applicability of the data to their own studies.

Summary

Investing in a sound data management strategy will improve data quality across all of an organization's projects. A data management approach that is based on well-defined quality objectives, thorough planning, coordination between teams, and the intelligent use of technology will improve data longevity and usability while reducing costs associated with fixing data errors and maintaining data availability.

References: Lake Michigan Mass Budget/Mass Balance Work Plan. GLNPO, U.S. EPA.

INTEGRATING IT AND QS
Information Technology and Quality Must Work Together

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Rapid progress in information technology, telecommunications and communications technology presents significant challenges for both quality and information technology (IT) professionals. Factors like the Internet and data storage have changed everything, and the pace seems so rapid. The estimated number of web pages grew from 130 sites in June, 1993 to 3.2 million in April, 1998. Just a few years ago, it seemed that data storage was measured in kilobytes and megabytes, while today we have data warehouses and data marts that exceed 100 terabytes. Systems must be up and running continuously. Security intrusions can damage data or even deny access. At the same time, IT provides unique opportunities to manage by fact, to standardize, to improve processes, and to help customers and solve their problems. We now can use spatial information management (SIM), geographic information systems (GIS), and business support systems (BSS) with database systems to support lots of mainstream operations and processes. New languages like XML (Extensible Markup Language) offer new solutions for data exchange.

For years, quality often took an outside role and failed to integrate itself into the business. IT has had a similar reputation, such as that of a "back office support organization." We mustn't repeat the past. The presentation will discuss and promote sharing of understanding in areas such as: reasons why and how the quality professional should keep up with developments in IT, why the IT and quality professional should work closely together, how the skills and experience that IT and quality professionals each possess can be used tp help the other out and help the business, and examples from the IT world on integration with quality such as how the IT professional acquires data for a data warehouse with quality in mind, deploying quality system documentation using an Intranet or Internet, and understanding the roles regarding a key integration topic by its name alone - software quality assurance.

Validating Existing Data in the Environmental Technology Verification Program

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Establishing the credibility of existing data is an ongoing issue, particularly when the data sets are to be used for a secondary purpose, not the original reason for which they were collected. If the secondary purpose is similar to the primary purpose, the potential user may have little difficulty establishing credibility since the acceptance criteria for both purposes should be similar. If the secondary purpose is different, data credibility may be more difficult to establish because the experiment generating the data may not have been conducted optimally for the secondary purpose and therefore all of the necessary quality assurance data ("metadata") may not have been collected. In either case, a process will be required to determine the acceptability of the data.

At the time the U. S. EPA Environmental Technology Verification (ETV) program was founded, similar certification and verification programs run by states or foreign countries routinely used existing data sets rather than generate data by testing for cost reasons. Therefore, the issue of whether existing data could be used in the ETV program immediately surfaced. In response, the policy and process for addressing existing data were written and published in Appendix C of the ETV Quality and Management Plan (Hayes et al., 1998). This paper will discuss how the ETV program determines the credibility of existing data offered to verify the performance of environmental technologies.

Introduction

The current official method for validating existing data in the Environmental Technology Verification (ETV) program is one example of how existing data can have a useful life beyond the project in which they were collected. Before the method is described, some terms need to be defined. *Validation* is the act of proving the veracity or falsity of data. *Existing data* are those which exist before the program or project that wishes to use them has begun. Also known as historical or secondary data, they are data to be used for a secondary purpose, one other than the original purpose for which they were collected. The ETV program is a 5-year pilot program established by EPA's Office of Research and Development (ORD) to verify the performance of emerging environmental technologies. Begun in 1995, it is currently in its final year.

To understand the ETV method for validating existing data, it is helpful to know how the program normally functions. EPA established partnerships with several independent third party organizations (such as nonprofit research institutions), usually through cooperative agreements and designated 12 topic-specific pilot programs capable of testing a variety of technologies. The partnerships run the pilot programs for the purpose of verifying the performance of emerging environmental technologies. Verification organization partners must have written quality systems. The process for verifying a technology usually begins with the production of a written generic testing protocol for a specific class of technologies. Vendors are then publically solicited through *Commerce Business Daily*, mailings,

advertisements, and word of mouth to apply for testing of their candidate technologies. Once the vendors are signed on, specific quality assurance (QA)/test plans are written and accepted by all interested parties. Testing and data collection are performed by the independent, third-party partner organization. Costs of testing are shared by EPA and the vendors. The cost for the first round of verification testing for a given type of technology is borne mainly by EPA; however, the vendor share increases for subsequent rounds of testing. Quality systems, QA/test plans, testing, and data reports are all closely monitored and audited by EPA and the partners. The result is a publically available combined Verification Statement/Verification Report detailing the results of the testing and the performance that can be expected of the technology under the conditions it was tested.

Why not use existing data?

Almost immediately upon establishment of the ETV program, vendors raised the question: "Why test at all?" Why not use existing data like the program run by the State of California that certifies environmental technologies, or the verification program sponsored by Canada but financed by vendors, to verify the performance of their technologies? Why not indeed? Valid arguments exist to advance this position. For instance, theoretically it is less expensive to validate existing measurements than to make new ones. Data which already exist are available more quickly than data which still have to be collected. Further, data collected over a time span of a year or more should be more representative of the performance of a technology that those collected over a few days. Clearly, the issue needed to be addressed.

The problem

For existing data to compete on the same level as data collected in the program, it was only fair that they be made to conform to the same rules. That is, for existing data to be accepted for verification of performance of an environmental technology, the testing and data collection must have been performed at the same level of QA review and assessment as the verification testing and data collection for other technologies in its class. The basic problem was: how does the ETV EPA/cooperator partnership determine that an existing data set is comparable to a data set produced by EPA-sponsored ETV testing?

The solution

The solution was to establish written requirements in which the process to determine whether requirements are met is described. A key requirement was to establish an authoritative entity to provide judgment and adjudicate disputes. The written requirements are found in Appendix C of the ETV Quality and management Plan (Hayes et al.,1998). In it, the policy and process for validating existing data are described. The policy requires that data to be considered for use to *replace verification testing* undergo a rigorous process of evaluation using stringent criteria.

Policy

Guidelines to qualify existing data for verification purposes are provided as follows:

1. Use qualified reviewers.

2. The documentation provided must be sufficient to assess the quality, usability, and comparability of the data to the required measurements in the ETV generic protocol conducted for the technology class.
3. The data must meet minimum quality acceptance criteria.
4. The data must have been objectively collected, independently of the vendor.
5. The data must have be collected under a well-defined, documented quality system. It is suggested that a suitable quality system is one modeled after Standard E-4 (ANSI/ASQC, 1994), or Standard 9000 (ISO, 1987). Other similar quality systems may be acceptable at the discretion of the reviewers.

Process

The process for validating existing data consists of several steps. The first is a screening step to identify and qualify the data to be reviewed. The vendor submits the data to the ETV verification organization who reviews it to determine if it meets minimum general acceptance criteria plus any specific criteria added by the pilot stakeholder group. The data meet qualifications if the testing was performed by an objective, third party tester/evaluator and was universally available to qualified parties. The measurements must have been performed under a quality-managed program. All pertinent information, including protocols and test plans, is available and reproducible. The data must be of acceptable quality for verification, and the results publically available. Quality acceptable for verification means that the technology is based on sound scientific principles, the data were collected under appropriate and clearly defined conditions, the data are of known and acceptable quality, and there are sufficient data points to verify performance.

If the data cannot pass the screening, the validation process stops. If the partner believes that the data may withstand the validation process, then a data evaluation panel (DEP) is convened. The DEP has the authority to recommend acceptance or rejection of the data. Three objective, independent reviewers sit on the DEP, one from EPA, one from the partner organization, and an outside expert. The reviewers must be credible, experienced, knowledgeable, and qualified in the technical area critical to the technology under evaluation. They may not have any affiliation with the manufacturer or vendor of the technology under evaluation, nor have been associated with the project that produced the data under consideration. The DEP determines whether the data meet requirements. It reviews and approves the criteria for acceptance of the data, follows the procedures and criteria established for ETV verification testing, evaluates the technology using the partner's screening report and other available documents, and provides an acceptance recommendation. The result is a Verification Statement/Verification Report (VS/VR) signed by EPA and the verification partner, the same document as that resulting from verification testing.

Why this process and who uses it?

Why have this lengthy and costly process? Without it, ETV might make decision errors. The consequences could be serious, resulting in verification of fraudulent claims, litigation, and loss of credibility for the ETV program, the verification partner organizations, and EPA. Of the 54 verifications performed to date, however, the ETV website (http://www.epa.gov/etv/) indicates that not one vendor has chosen to rely exclusively on existing data. Several reasons can be suggested. The time and cost

are likely to equal those of testing, thereby eliminating almost any advantage. The data may not meet acceptance criteria such as not being collected by an independent entity having a written quality-managed system. The data may provide evidence but not enough to warrant verification. The vendor may go to a lot of trouble, only to have the data eventually rejected.

Why have a process no one uses? It provides a legitimate, uniform method to validate existing data that requires it to meet the same criteria as those acquired through testing. It further provides protection against those who seek an easy way to circumvent testing. Because ETV has not used existing data as the sole verifier of technology performance does not mean that it is not used in ETV. Existing data are used for planning and to augment verification data collected through testing. These data are not subjected to the lengthy validation process since they can be validated by the data collected through testing.

Conclusions

A policy and a process have been developed and described for analyzing existing data. They are useful for acceptance of data offered in lieu of those which would have been acquired by ETV testing. A credible, uniform procedure is in place, even if never used for evaluation of data. It satisfies those who have existing data and want a method in place to use them, and it satisfies those who choose to test since it is stringent enough to level the playing field.

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Software for Considering MQOs within a DQO Framework

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April 5, 2000

Outline

- Definitions
- DQOs as driver for MQOs
- Factors that affect MQOs
- Ways to Search for Optimal MQOs
- Demonstration of Visual Sampling Plan MQO Module

Definitions

- DQOs: Data Quality Objectives Quantitative criteria that define appropriate types of data to collect and tolerable decision errors.
- MQIs: Measurement Quality Indicators Precision, Accuracy, Representativeness, Comparability, Completeness, Sensitivity
- MQOs: Measurement Quality Objectives Targets values for the MQIs (e.g., Precision should be + or - 10%)

Components of DQOs affecting MQOs

n sample size
σ standard deviation (total variability)
α Type 1 decision error
β Type 2 decision error
Δ difference to detect

....ugh, not THOSE again!

DQOs and MQOs

DQOs		MQOs
How good does the decision have to be?	→	How good do the data have to be?

DQOs are the driver for MQOs

MQOs = Used in interpreting the degree of acceptability or utility of data

What Affects Precision?

For individual measurements (x_i)

- inherent variability, measurement variability
- as n increases, get better estimate of σ_x
- lab may report $x_i \pm k\,\sigma_x$, manufacturer may report σ_x

For estimates of the sample mean (xbar)

- number of observations that contribute to sample mean
- as n and no. of replicates increases, get smaller σ_{xbar}
- analyst may report xbar $\pm$ k σ_{xbar}
- Remember $\sigma^2_{xbar} = \sigma^2_x / n$

Components of Variability

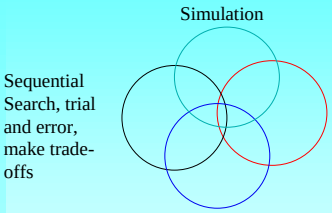
- Field, physical support, handling, subsampling, handling, lab, instrument variability, …..
- In most cases, components of variability are additive
- For sample mean, total variability is

$$\sigma^2_{xbar,\ total} = \sigma^2_{samp}/n + \sigma^2_{sub}/nm + \sigma^2_{meas}/nmr$$

n =field samples, m=no. of subsamples, r=no. of replicate analyses

Battelle PNNL DQO Programs

How to translate DQOs into MQOs



Battelle PNNL DQO Programs

What is VSP

- Software tool developed for DOE by PNNL, ORNL to facilitate design of environmental sampling plan
- Calculates no. of samples, no. of replicate analyses to meet DQO error limits, delta to detect
- Interactive, visual, modular, considers cost, play "what if" scenarios

Battelle PNNL DQO Programs

What demo will show

- How to search for best measurement instrument performance, given DQOs
- How to trade off less, more accurate (and costly) measurements for more, less accurate (and less costly) measurements. Look at total, integrated performance of design
- When to do replicate analyses

Battelle PNNL DQO Programs

Conclusions

- MQOs are tied to DQOs
- VSP is software tool to help implement MQOs based on DQOs
- Other resources are under development (G5i, MARLAP, PBMS implementation plans, etc.)
- Download VSP at:
  http://etd.pnl.gov:2080/DQO/

Battelle PNNL DQO Programs

Automated Reconciliation of Data with Measurement Performance Criteria for Environmental Technology Verifications

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Abstract: This paper describes the development and structure of measurement data spreadsheets and assessment spreadsheets used for automated reconciliation of data with measurement performance criteria. It touches on underlying quality system issues such as the need for quantitative and measurable criteria and for integration of quality procedures in the measurements system. Finally, the paper will discuss the relative costs of quality assurance and other components of the verification testing program.

Environmental Technology Verification Program

One of the most frequently mentioned impediments to the commercialization of innovative environmental technologies has been the lack of acceptance of vendor performance claims. EPA established the Environmental Technology Verification (ETV) Program to verify the performance characteristics of commercial-ready environmental technologies in an objective and quality-assured testing program (1,2). The goal is to disseminate credible verification results to those who buy, use or permit these technologies. EPA has funded twelve pilot programs over a 5-year pilot period to test the hypothesis that verification testing by independent, third-party partner organizations will accelerate the implementation of these technologies. The programs include air pollution control technologies (APCT), drinking water technologies, pollution prevention and waste treatment, and hazardous waste site characterization and monitoring.

The ETV program employs a high-level of quality assurance (QA) to ensure that verification results are credible. The ETV quality and management plan for the pilot period describes quality systems that have been developed within EPA and partner organizations (3). The plan complies with American National Standard ANSI/ASQC E4-1994 for quality systems for environmental data collection and environmental technology programs (4). EPA reviews and approves the quality systems documents and the verification statements and reports that are developed by partner organizations. Additionally, EPA conducts independent management systems reviews and technical audits of the partner organizations.

Pilot Program for Air Pollution Control Technologies

Research Triangle Institute (RTI) operates the pilot program for APCT, which includes several technology classes, such as paint overspray arrestors (POAs), baghouse filtration products, and add-on nitrogen oxides (NO_X) controls. RTI developed an E4-compliant quality management plan to describe its overall quality system for the pilot program (5). A technical panel of experts assists RTI to develop a generic verification protocol (GVP) for each class (6). Each GVP specifies data quality objectives, test/QA plans. independent audits, and report review/approval requirements. Each organization

conducting verification tests prepares a test/QA plan, which describes how it will produce data having the GVP's specified quality (7). The APCT program and each organization has a QA officer to oversee its own quality system.

Verification Testing of Paint Overspray Arrestors

EPA established a National Emission Standard for Hazardous Air Pollutants (NESHAP) for aerospace manufacturing and rework facilities to control chromium emissions. POAs are used to collect particulate overspray from spray painting. EPA specified minimum size-selective filtration efficiencies and specified Method 319 to measure the efficiency (8). This method may be used by filter manufacturers and distributors, spray booth suppliers, or owners of affected sources to certify the efficiency of their filters. The POA GVP is based on EPA Method 319.

During each of 15 different verification tests, an optical particle counter (OPC) makes 300 size-selective, particle concentration measurements upstream and downstream of a POA. Both liquid and solid aerosol particles are used in the testing, which occurs in a test rig that is similar to a wind tunnel. These OPC measurements are used to calculate the POA's size-selective filtration efficiency. The OPC measurements are summarized in a verification report, which is reviewed, approved, and published by EPA. The POA QA officer is responsible for reviewing these data and reconciling them with the measurement performance criteria (MPC). This task is made easier by the standardization of the data spreadsheets and the development of an assessment spreadsheet that scans these spreadsheets for attainment of MPC.

Measurement Performance Criteria

EPA Method 319 MPC were adopted for POA verification testing in the GVP. They address OPC-specific parameters, such as the minimum particle counts per size-selective channel and an accuracy check using a reference filter medium. They also address parameters specific to the test rig, such as temperature and humidity limitations and the accuracy and precision of air flow measurements. Finally, they specify minimum size-selective filtration efficiencies for POAs that can be used to comply with the emission limitations of the NESHAP.

These MPC present quantitative limits for measurable parameters referenced to defined standards. Explicit procedures are given to calculate whether the MPC have been attained. MPC must be realistic, germane, and specific to the measurement system being assessed. Technical personnel who are involved in conducting the tests and the QA officers who are involved in assessing data quality must understand clearly the requirements for producing valid data .

Standardized Data Spreadsheets

Full documentation of all information necessary to validate data and to document conformance with the quality system is assembled in a stand-alone file, which is reviewed by the QA officer. A standardized data spreadsheet was developed to provide a rapid, inexpensive, and high-quality review of verification

data (see Table 1). It accepts text data from the OPC in a standard format. Test-run identification is encoded in the filenames to ensure full data traceability. Summary calculations, including quality metrics, are then performed automatically. Initial "pass/fail" decisions are made by the software, which allows technical personnel and the QA officer to focus on possible trouble areas or to peruse data in an informed manner. Data are updated as changes are made, and the updated files are included in the electronic data package.

Verification data are formatted as one test per spreadsheet. Typically, 15 data spreadsheets plus the one summary spreadsheet are stored on a 3 ½" floppy disk. In addition to the verification data, three distinct types of quality metrics are inserted into the spreadsheets. The first type are specifications for the quality of verification data (e.g., the standard deviation of aerosol penetration). The second type addresses instrument calibration. The third type documents whether the test rig is capable of meeting the operational specifications of the POA GVP.

Automated Reconciliation of Data

Design criteria for a spreadsheet that reviews verification data rapidly and reliably include:

- no revision of the data spreadsheets;
- all data processed in a standardized, traceable process without manual intervention;
- all summary data obtained from the data spreadsheets; and
- calculations and macro instructions kept to minimal complexity.

Key requirements in the capability to develop this type of assessment spreadsheet are that the data are supplied in rigidly standard format, and the spreadsheet software must readily accommodate linkages to multiple cells in multiple data spreadsheets. Good practices by the technical personnel make attainment of the standard format requirement possible. Currently available spreadsheet software allow for easy linkages.

The POA assessment spreadsheet is a simple three-worksheet notebook that indirectly references the specified cells in the data spreadsheets based on the data contained in the summary spreadsheet. One worksheet reconciles the verification data (see Table 2); the second worksheet reconciles calibration information (i.e., calibration date and quality), and the third worksheet reconciles test rig qualification data (i.e., qualification date and quality).

The process begins by copying the set of data spreadsheets into their own subdirectory, and then opening a copy of the assessment spreadsheet. This spreadsheet extracts the test-run filenames from the summary spreadsheet and inserts them into a short macro (the only one) which sequentially opens each of the identified data spreadsheets. All calculations are then performed by linking to the appropriate verification data and by reconciling these data with the MPC. This reconciliation is completed in approximately 5 seconds. The QA officer then reviews the assessment spreadsheet and decides what specific data to evaluate manually.

Assessment Results

The first round of POA verification testing was conducted in the spring of 1999 and involved five POAs. The second round was conducted in the fall of 1999 and involved six POAs. The standardized spreadsheets for POA verification testing were developed before the first round. The reconciliation of verification data with MPC was performed manually during the first round. The spreadsheets for automated reconciliation of data were developed for, and were used during, the second round.

All POA verification testing results from both rounds attained their MPC. The automated reconciliation during the second round revealed several minor problems with transferring data to the standardized spreadsheets. One example is an error flag for the standard deviation of downstream OPC measurements. This apparent failure was flagged in the spreadsheet and inspection of the verification data indicated all the measurements were zero. The standard deviation of a series of zero values should result in a calculation error.

Cost Analysis

Based on its testing experience, RTI has developed proprietary cost and labor estimates for EPA Method 319 testing and the corresponding testing under the ETV program. Not counting those costs associated with managing the APCT pilot program at EPA and RTI, developing the quality system and calibrating instruments, the cost of the POA verification testing under the ETV program is approximately three times the cost of a Method 319 test. Because the MPC are the same for both types of tests, the increased cost cannot be attributed to the need for a higher level of measurement data quality.

The increased cost of POA verification tests is attributed largely to the increased documentation requirements. RTI personnel estimate that about one-quarter is due to increased professional oversight during POA testing, about one-half is associated with increased report preparation costs to get the first draft into review, and about one-quarter is associated with document revisions and handling resulting from the multi-level EPA reviews.

The total labor estimate for the POA verification testing can be broken down as follows:

Activity	Percent of Hours
POA verification testing	31
Internal data review	6
Direct quality assurance	6
ETV report preparation	37
Internal report review	14
Migration to Internet	6

These labor estimates indicate that the direct cost of quality assurance is not a major driver of the increased cost of the POA verification testing. The use of spreadsheets for the automated reconciliation of verification data with MPC is one reason for the relatively low cost of quality assurance in the POA verification testing program.

Disclaimer

Although the information in this document has been funded wholly or in part by the United States Environmental Protection Agency through Cooperative Agreement No. CR 826152-01-0 to Research Triangle Institute, it has not been subjected to Agency review and therefore does not necessarily reflect the views of the Agency and no official endorsement should be inferred.

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	Particle counts in channel (1-minute samples @ 7.1 L/min)					
OPC channel number	1	2	3	4	5	6
Minimum diameter (µm)	0.45	0.59	0.73	0.80	1.01	1.44
Maximum diameter (µm)	0.59	0.73	0.80	1.01	1.44	1.86
Upstream background	0	0	0	0	0	0
Upstream	9906	15210	4721	8631	13060	7586
Upstream	10140	15260	4804	8950	13360	7959
Upstream	10410	15560	4867	9101	13840	8060
Upstream	10020	14890	4814	8556	13350	7905
Upstream	10100	14850	4829	8570	13280	7877
Upstream	9782	14920	4769	8396	12730	7719
Upstream background	0	0	0	0	0	0
Downstream background	0	0	0	0	0	0
Downstream	12	21	2	11	12	6
Downstream	10	14	3	9	17	8
Downstream	8	19	4	5	14	8
Downstream	7	14	6	10	14	10
Downstream	9	18	4	8	15	8
Downstream	12	17	2	7	19	11
Downstream background	0	2	0	2	1	0
Measured penetration (P)	0.00	0.00	0.00	0.00	0.00	0.00
P_{100} correction values	1.01	1.00	1.01	1.00	1.01	1.01
Corrected penetration (P_{corr})	0.00	0.00	0.00	0.00	0.00	0.00
Corrected efficiency (%)	100	100	100	100	100	100
Total upstream counts (TUC)	99149	148690	47103	84578	129190	76656
MPC for TUC	> 500	> 500	> 500	> 500	> 500	> 500
Does TUC meet MPC?	Yes	Yes	Yes	Yes	Yes	Yes
Standard deviation (SD) of P_{corr}	0.00	0.00	0.00	0.00	0.00	0.00
MPC for SD	<0.10	<0.10	<0.10	<0.10	<0.10	<0.10
Does SD meet MPC?	Yes	Yes	Yes	Yes	Yes	Yes

Table 1. Truncated OPC Data Spreadsheet

Reviewer: C.E. Tatsch		Test Type					Temp		RH	
Aerosol	Test No.	None	POA	HEPA	Ref Filt	Avg) P	Min (F)	Max (F)	Min (%)	Max (%)
Solid Phase	09099908	X				- - -	71	73	46	60
	09099909				X	- - -	73	74	43	50
	09099906	X				- - -	74	75	37	40
	09099907		X			0.1	75	77	40	45
	09099910	X				- - -	74	77	40	43
	09099911		X			0.1	75	77	44	45
	09109901	X				- - -	75	76	40	41
	09109902		X			0.1	75	77	37	42
	08319904			X		- - -	74	75	41	42
Liquid Phase	09089908	X				- - -	75	76	40	41
	09089909		X			0.06	75	76	39	40
	09099902	X				- - -	75	77	37	42
	09099903		X			0.105	73	73	42	53
	09099904	X				- - -	73	74	39	42
	09099905		X			0.1	75	76	39	40
					Max			77		60
					Min		71		37	
					MPC		> 50	< 100	> 0	< 65
					MPC met?		Yes	Yes	Yes	Yes
					100% P			Std Dev P		

Aerosol	Test No.	OPC zero	Min Counts	0% P	0.3 - 1 µm	1 - 3 µm	3 - 10 µm	0.3 - 3 µm	3 - 10 µm	Max Conc
Solid Phase	09099908	2	1754	- - -	0.01	0.01	0.09	0.04	0.08	16.7
	09099909	1	1812	- - -	- - -	- - -	- - -	0.03	0.05	16.5
	09099906	6	1748	- - -	0.01	0.02	0.10	0.08	0.12	17.9
	09099907	3	1907	- - -	- - -	- - -	- - -	0.03	0.01	16.9
	09099910	3	1868	- - -	0.02	0.02	0.07	0.06	0.13	17.3
	09099911	3	1833	- - -	- - -	- - -	- - -	0.03	0.01	17.1
	09109901	2	1611	- - -	0.02	0.02	0.09	0.08	0.15	17.5
	09109902	3	1651	- - -	- - -	- - -	- - -	0.02	0.01	17.8
	08319904	2	1849	0.00	- - -	- - -	- - -	0.00	Error	17.7
Liquid Phase	09089908	3	1392	- - -	0.01	0.01	0.34	0.08	0.15	16.0
	09089909	3	1290	- - -	- - -	- - -	- - -	0.06	0.01	16.3
	09099902	1	1578	- - -	0.01	0.03	0.03	0.04	0.11	16.7
	09099903	4	1679	- - -	- - -	- - -	- - -	0.05	0.02	15.8
	09099904	2	1622	- - -	0.02	0.02	0.06	0.04	0.11	17.1
	09099905	1	1805	- - -	- - -	- - -	- - -	0.04	0.01	16.4
Max		6		0.00	0.03	0.03	0.34	0.08	Error	17.9
Min		1		0.00	0.01	0.01	0.03	0.00	Error	15.8
MPC		< 50	> 500	< 0.01	< 0.10	< 0.25	< 0.50	< 0.10	< 0.30	< 23
MPC met?		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Error	Yes

Table 2. Truncated Data Reconciliation Spreadsheet

GEOGRAPHIC INFORMATION SYSTEMS: QA CONSIDERATIONS

Session Chair: George M. Brilis

Geographic Information Systems (GIS) are increasingly becoming an important tool in making Agency decisions. Quality Control and Quality Assurance is required to be integrated the planning, implementation and assessment of GIS databases. The presentations in this session will address some of efforts being by various programs and offices to improve the quality of GIS outputs and will also examine how the quality of GIS affects enforcement of environmental regulations.

The EPA GIS-QA Team: Promoting Quality Assurance in the GIS Community George M. Brilis, EPA/NERL/ESD-LV

The EPA's new initiative, the Geographic Information Systems - Quality Assurance Team (GIS-QA), is committed to working with all organizations to ensure that spatially related tools, such as the LDP, are supported. An overview of the EPA GIS-QA Team and primary components of the Locational Data Policy will be presented.

Who, What, Why – Quality Assurance Issues in Dynamic GIS Environments David Hansen, U.S. Bureau of Reclamation

GIS is a dynamic environment where features from one data set can be selected out and combined with features from other data sets to produce entirely new themes. GIS is a tool which is now available at the computer desk top. It is a main component in many decision support systems. It is being actively employed as a query and analysis tool on the Web. We have standards for documenting GIS data and a variety of tools to assist in that process for completed data sets. However, we lack guidance and robust tools for identifying what took place in the dynamic environment of the desk top, the Web, and frequently in our decision support systems. Frequently questions about the results that we get back from these interactive GIS systems can be answered by knowing:

6. What processes took place,
7. What data sets were involved in the processes,
8. What the processing environment was for the GIS system,
9. Why the processes were selected,
10. Who actually ran the processes.

This presentation examines these issues in the context of our existing GIS standards for lineage documentation. It focuses on existing GIS interactive applications and tools for identifying and documenting processes taking place in these applications

Geo-Referencing Initiatives Milo Anderson, Sarah Lehmann/Region 5, Michael Plastino/EPA Office of Water

The purpose of this presentation is to:

- Highlight the need for a more comprehensive integration of EPA's environmental information;

- Discuss the benefits and limits of current standards and policies on information integration;

- Introduce the need to create a comprehensive EPA Geo-Referencing Framework to overcome current limits; and

- Present Office of Water efforts at initiating a geo-referencing framework through reach and watershed indexing.

Using GIS in Environmental Litigation - Applications, Solutions, and Quality Issues Robert J. van Waasbergen, President, Applied Environmental Data Services

GIS has become a common tool in environmental management and enforcement. Only in the last few years, however, has the technology come into use directly by litigators working on environmental cases. This presentation explores how GIS is being used in law firms to manage and support cases. In general, there is a progression in the sophistication of use. This ranges from building courtroom exhibits from pre-packaged data sets, to integrating and analyzing data sets of disparate origin, and finally to full-scale information-management. These applications require attorneys, paralegals and technical experts to be aware of data quality issues at different levels.

Metadata Information Management Cheryl Itkin, EPA/NCEA

The EPA's Environmental Information Management System (EIMS), developed by the EPA Office of Research and Development/National Center for Environmental Assessment, is the Agency's level 2 metadata repository. EIMS serves as the agency tool for metadata creation, management and dissemination. It is accessible via the WWW and is growing every month. EIMS is fully compliant with the Federal Geographic Data Committee Content Standard for Geospatial Metadata and is a node on the National Spatial Data Infrastructure. The content of EIMS is not limited to Geospatial metadata and includes any information about scientific projects, documents, data and tools.

QA Considerations in GIS Information Management Karl A. Hermann,
Regional GIS Coordinator, EPA Region 8

The management of geographic information presents some unique considerations with respect to quality assurance. The considerations include spatial data locational references of projections, coordinate systems, and datums. The importance of scale and intended use are also examined. Finally, data relationships, data structure, and documentation are addressed.

Software Answers to QA/QC Output for GIS.. Mitch Beard, President, EarthSoft Inc.

Producing QA/QC reports for GIS related products that embraces the federal standards can be cumbersome and time-consuming. Various software products now exist that take into account the EPA DQO process. And produce QA/QC outputs that can be electronically “tagged” to GIS, analytical chemistry and other products.

Spatial Accuracy as a Critical GIS-QA Element George M. Brilis, EPA/NERL/ESD-LV

Onsite analyses are critical to making timely decisions. The results of these decisions may not be realized for many years. In order to increase the value of onsite analyses and to create and utilize

meaningful environmental models, the EPA developed and implemented a Locational Data Policy (LDP).

The intent of this policy is to extend environmental analyses and allow data to be integrated based upon location, thereby promoting the enhanced use of EPA's extensive data resources for cross-media environmental analyses and management decisions. This policy applies to all EPA organizations and personnel of agents (including contractors and grantees) of EPA who design, develop, compile, operate or maintain EPA information collections developed for environmental program support.